The identification and management of prodromal symptoms in bipolar affective disorder: The role of individual, disorder, and treatment-related factors.

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Abstract

Background: Traditional psychosocial treatments have been adapted for use with individuals with bipolar affective disorders due to the limited prophylactic nature of pharmacotherapy and the recognition of the role of psychosocial factors in the course of this disorder. Psychosocial interventions that include a prodromal monitoring and management component have been empirically shown to be an effective adjunct to medication for the treatment of bipolar disorder.

Aims: There is a deficit of quantitative research that examines the impact of individual-related (e.g. age, self-efficacy), disorder-related (e.g. time since diagnosis, experience of prodromal symptoms) and treatment-related (e.g. level of psychosocial input) factors on individuals' ability to manage this disorder via the use of prodromal monitoring. The current research aimed to investigate factors that are associated with the identification and management of prodromal symptoms.

Method: Participants completed five self-report measures in order to provide information on their experience of prodromal symptoms, current mood state, general self-efficacy, view of social support from significant others, and demographic and clinical-related variables. The data were collected from 101 participants, 58 of whom were female. The sample consisted of individuals with a diagnosis of bipolar disorder type I and II.

Results: Univariate and bivariate analyses were used to explore the relationship between individual, disorder, and treatment-related variables associated with participants' experience of bipolar disorder. Variables that were significantly associated with participants' perception of their ability to identify and manage prodromes were further investigated using ordinal logistic regression analyses.

The results indicated that general self-efficacy and prodromal-specific help from significant others were associated with an increase in participants' perception of their

ability to identify manic and depressive prodromal symptoms. General self-efficacy was also associated with participants' view of their ability to manage cognitive and behavioural prodromes. Experience of prodromal symptoms (e.g. consistency of symptoms experienced, type of prodrome experienced) was associated the participants' perception of their ability to identify and manage prodromes. In general, disorder-related variables (e.g. time since diagnosis, mood state, diagnosis type, and number of episodes experienced) were not significantly associated with the participants' view of their ability to identify and manage prodromal symptoms. Individual-related variables such as gender and age, however, were associated with prodromal identification.

Conclusion: The results indicated the need to consider constructs such as general self-efficacy and experience of prodromal symptoms (e.g. consistency of symptoms, types of prodromes experienced, and ability to recognise prodromes when they first present) when helping patients to learn how to identify and manage prodromal symptoms. In addition gender differences and the role of help from significant others were highlighted as variables that should be considered when using prodromal monitoring approaches with patients with bipolar disorder. Limitations of the research are reviewed in relation to the methodology used. Clinical implications and directions for future research are considered.

1.0 INTRODUCTION

1.1 Overview

This chapter presents information on the course of bipolar affective disorders, diagnostic criteria, and potential social and emotional disorder-related consequences. Aetiological and maintenance factors are also discussed with reference to psychosocial factors. Information on treatment approaches for bipolar disorders (e.g. Cognitive Behavioural Therapy and Family Focused Therapy) is then provided. Lastly, the role of prodromal monitoring, as a self-management approach, is discussed.

1.2 Bipolar disorder and diagnostic criteria

The clinical course of bipolar disorder can range from mild depression and brief hypomania to severe psychotic mania or depression (Emilien *et al.,* 2007). The manic phase lasts for a minimum of one week and is characterised by abnormally and persistently elevated mood (APA, 2000). During a manic episode cognitive, behavioural, and affective symptoms can be experienced. Common manic symptoms experienced by individuals include extreme optimism, increased self-worth, racing thoughts, reduced need for sleep, increased activity, agitation, restlessness, inability to concentrate, irritability, and poor judgement. During the depressive phase, which lasts for a minimum of two weeks, cognitive, behavioural, and affective symptoms can also be experienced (APA, 2000). Common depressive symptoms include low self-esteem, suicidal thoughts, difficulty concentrating, sense of hopelessness, changes in eating and sleeping patterns, and a loss of interest in enjoyable activities. Individuals can also experience mixed episodes which are characterised by the presence of both mania and major depression for at least a one-week period (APA, 2000).

The diagnostic criteria for bipolar disorder were first provided in the American Diagnostic and Statistical Manual in 1980 (DSM-III: American Psychiatric Association, 1980). Diagnostic criteria were later included in the World Health Organization Classification of Diseases (ICD-10, WHO, 1992). The DSM-IV (1999) diagnostic

criteria tend to be used in this research area. For the DSM-IV diagnostic criteria for manic, depressive, mixed and hypomanic episodes refer to Appendix 1.

While the potential for there to be up to seven subtypes of bipolar disorder has been recognised (Akiskal & Pinto, 1999), this disorder is generally discussed with reference to two types – bipolar I disorder and bipolar II disorder. In order for a diagnosis of bipolar I disorder to be given, an individual has to have had at least one manic episode during their psychiatric history in addition to recurrent depressive episodes. Individuals diagnosed as having bipolar II disorder will have experienced recurrent depressive episodes with hypomanic episodes (i.e. episodes that do not reach the criteria for manic episodes, APA, 2000). When individuals experience four or more episodes in a 12-month period they are given a rapid cycling specifier (APA, 2000).

1.2.1 Issues associated with the diagnosis of bipolar disorder

Bipolar disorder is commonly misdiagnosed and accurate diagnoses can be subsequently delayed over 10 years (Hirschfeld, 2001). Ruggero *et al.,* (2010) carried out a prospective study in which the diagnostic consistency, in a first admission sample (N = 195), was reviewed on four admission occasions over a 10-year period. They concluded that 49.3 percent of the participants were inconsistently diagnosed at least once in the course of 10 years.

Delays to a bipolar disorder diagnosis or inaccurate diagnoses may result from disorder and or clinical-related issues. For example, patients may fail to seek help when they are manic or hypomanic because these mood states are not recognised as abnormal (Hirschfeld, 2004). When individuals first present with depression, clinicians may not enquire about past manic symptoms (Brickman *et al.,* 2002) or patients may not recall or report manic episodes. Other factors that can result in diagnostic inconsistency include greater number of psychiatric symptoms, a high presence of psychotic symptoms, a low level of general functioning, and a change in presentation over the course of the disorder (Ruggero *et al.,* 2010). While there are clear diagnostic criterion for the mood states

associated with bipolar disorders (i.e. DSM-IV, APA, 2000) the disorder's characteristics and course are complex and vary among individuals (Emilien *et al.,* 2007): the idiosyncratic nature of this disorder can further complicate a diagnosis.

The high rate of co-morbidity observed in individuals with bipolar disorder can also complicate accurate diagnosis. McElroy *et al.,* (2001) examined rates of co-morbidity in a sample of 288 outpatients with bipolar I and II disorder. They concluded that 65 percent of the sample met criteria for Axis l disorder, 42 percent for anxiety disorders, 42 percent for substance misuse, and 5 percent for eating disorders. Other common co-morbidities include personality disorder (Akiskal *et al.,* 1985) and attention-deficit hyperactivity disorder (ADHD, Oswald *et al.,* 2007).

1.3 The course of bipolar disorder

The prevalence of bipolar disorder is estimated at 0.8 percent to 1.6 percent of the population (e.g. Kessler *et al.*, 1997). Research places the average age of onset between 19 years (Burke, 1990) and 28 years of age (Goodwin & Jamison, 2007). The frequency of which bipolar disorder first presents declines with age: 6 percent to 8 percent of first time presentations develop in persons aged 60 years and older (Emilien *et al.,* 2007). There is no discrepancy between prevalence rates for males and females for bipolar I disorder. More females than males, however, are thought to suffer from bipolar II disorder (Oswald *et al.,* 2007). In addition, more females are given a rapid cycling specifier (Emilien *et al.,* 2007).

Manic and depressive episodes are generally recurrent: for example, more than 90 percent of individuals who have a single manic episode will go on to have future episodes (Gitlin *et al.,* 1995). It is estimated that individuals will experience a mean of eight episodes (five manic and three depressive) during the course of their illness (ten Have *et al.,* 2002). However, between 10 percent to 15 percent of patients will have more than 10 episodes in their lifetime (Goodwin & Jamison, 2007). There is a positive linear relationship between the number of episodes experienced and relapse rates (Maj,

1999). Estimates place relapse rates at 40 percent in a 1-year period, 60 percent in a 2-year period, and almost 75 percent within 5-year period (e.g. Tohen *et al.,* 1990). It is worth noting that when the number of episodes experienced is assessed for research or audit purposes hospital admissions tend to be used as of measure of relapse. Therefore relapse rates may be higher as episodes managed within the community (e.g. by home treatment teams) may not be included in such figures. Information regarding the potential social and emotional impact of bipolar disorder is presented in section 1.4.

1.4 The social and emotional impact of bipolar disorder

Bipolar disorder is a severe condition that is associated with high levels of functional impairment, morbidity, and suicide (Oswald *et al.,* 2007). This disorder can have a detrimental effect on social functioning due to substantial impairments in work, family, and social relationships even after acute symptoms have resolved (Keck *et al.,* 1998). Between 30 percent and 60 percent of individuals with bipolar disorder fail to regain full functioning in occupational and social domains when in remission (MacQueen *et al.,* 2001); this may be due to the high rate of inter-episode symptoms (e.g. poor sleep) experienced by individuals with bipolar disorder (e.g. Gitlin *et al.,* 1995).

Repeated hospitalisations and recurrent episodes are highly disruptive to the patients' functioning in everyday life (Lam *et al.,* 2000). High rates of divorce (Kessler *et al.*, 1998) and unemployment (Goldberg *et al.*, 1995) are also observed in this group. Furthermore, individuals with bipolar disorder experience a high rate of stigmatisation (Hayward *et al.*, 2002).

Individuals with bipolar disorder are at increased risk of suicide and self-harm (Novick *et al.,* 2010). Approximately 25 percent to 50 percent of individuals with this disorder attempt suicide on one occasion (Jamison, 2000). A recent meta-analysis concluded that there is no difference in the risk of suicide for individuals with bipolar I and II disorder (Novick *et al.*, 2010).

Bipolar disorder is viewed as a debilitating chronic mental illness (e.g. Oswald, *et al*., 2007). Consequently, pharmacotherapy and psychosocial therapeutic approaches have been developed as treatment options. Information regarding these interventions is presented in section 1.5 and 1.6.

1.5.Pharmacotherapy treatment for bipolar disorder

Pharmacotherapy has historically been the first line treatment for bipolar disorder. This may be partially due to pharmacotherapy trials that demonstrate the prophylactic nature of Lithium and other anticonvulsant drugs in controlling cycling of mood states (Alloy *et al.*, 2005; Lam & Wong, 2005). A further explanation may involve the perceived aetiological factors (i.e. genetic and biological predisposition) associated with the onset of bipolar disorder and the subsequent influence this has had on the early development of treatment options. For example, bipolar disorder has a well documented genetic determinant as evidenced by adoption, family, and twin studies (Finn, 2007); heritability estimates are as high as 85 percent (McGuffin *et al.,* 2003).

While clinical drug trials demonstrate that Lithium, anticonvulsants, and antipsychotic agents are effective in stabilising acute symptoms of bipolar disorder maintenance, drug treatment is associated with relapse even when drug regimes are optimised (Miklowitz *et al.,* 2003). Approximately one third of bipolar disorder patients relapse while being prescribed Lithium treatment (e.g. Goodwin & Geddes, 2003). Figures for other pharmacological alternatives (e.g. Sodium Valproate and Carbamazepine) show a similar rate of relapse (Jones, 2004).

One explanation for the observed relapse rate may involve an inconsistent medication adherence that is common among people with bipolar disorder (Lam & Wong, 2005; Strober *et al.,* 1990). Non-adherence may be due to problems engaging in long-term medication use (e.g. issues with accepting the diagnosis, side effects of medication) or due to individuals choosing to stop medication in order to experience the mood state associated with manic episodes (Lam & Wong, 2005).

While it is generally agreed that there is a genetic and biological predisposition to bipolar disorder, these processes are unable to fully account for different expression, timing, and polarity of symptoms (O'Connell, 1986). Therefore, psychosocial theories have been postulated to explain aetiological-related aspects. For example, the stress-diathesis model (e.g. Frank *et al*., 1994) recognises the interaction between stressful life events and predisposed biological, biochemical, and neurological instabilities in the onset of bipolar disorder in vulnerable individuals (e.g. those genetically predisposed to developing the disorder). This model therefore recognises the contribution of both genetic and psychosocial factors in the development and subsequent maintenance of bipolar disorder.

In recent years, there has been a shift from the sole management of bipolar disorder via pharmacotherapy to a combined hierarchical treatment model in which pharmacotherapy and psychosocial interventions both feature. Prior to discussing psychosocial interventions, information pertaining to psychosocial explanations for the onset of bipolar disorder episodes is presented in section 1.6.

1.6 Overview of psychosocial models for bipolar disorder

The following five psychological models are associated with the onset and maintenance of manic and depressive episodes in bipolar disorder: Behavioural Activation/Inhibition Systems model (Gray, 1990); Cognitive Therapy model (Lam *et al.*, 1999); the Interpersonal and Social Rhythm Therapy approach (Frank, *et al*., 1999); the Interacting Cognitive Subsystems approach (Barnard, 1985); and the Schematic, Propositional, Analogical, Associative Representation Systems (SPAARS) approach (Power & Dagleish, 1997, cited in Power, 2005). Information relating to the Cognitive Therapy model and Interpersonal and Social Rhythm Therapy approach will be discussed as they are relevant to the current research. For a detailed discussion of the main psychological models refer to Power's (2005) theoretical critique.

1.6.1 Cognitive Therapy Model

The cognitive model for bipolar disorder is based on the cognitive model for affective disorder (Beck, 1967). The bipolar model also takes biological, psychological, and social elements into account (Wright & Lam, 2004). The model purports that the onset of manic and depressive episodes are associated with dysfunctional schemas, life events, goal attainment-striving, and the paradoxical nature of an individual's need for support versus a desire to be autonomous.

1.6.1.1 Depressive episodes

Within the model it is proposed that individuals with dysfunctional schemas are prone to develop depression (Wright & Lam, 2004). Dysfunctional schemas increase the likelihood of a negative appraisal of situations and contexts and can be activated during negative life events (Alloy *et al.*, 2005). Once an individual is in a depressed state and their dysfunctional schemas are activated, they can become biased towards making thinking errors and subsequently experience an increase in negative automatic thoughts. An increase in negative thoughts can serve to maintain a depressive state. When the individual is remitted, dysfunctional assumptions are assumed to be latent (Wright & Lam, 2004).

Anti-dependency beliefs have also been implicated in the onset and maintenance of depressive episodes. Lam *et al.,* (2004) found that remitted bipolar patients endorsed more anti-dependency beliefs than euthymic unipolar patients. It appears that individuals with bipolar disorder hold paradoxical beliefs concerning support of others as they may validate their personal worth via others while also maintaining a desire to be independent (Wright & Lam, 2004). This conflict may generate further perceptions of failure and frustration for individuals during depressive episodes. Therefore, autonomous beliefs are thought to act as a maintenance factor in bipolar depression (Wright & Lam, 2004).

1.6.1.2 Manic episodes

To account for the onset of manic episodes within the framework of the cognitive model, Lam *et al.,* (1999) highlighted the role of goal striving and attainment achievement oriented attitudes for individuals with bipolar disorder. It is purported that such attitudes lead to extreme striving behaviour and consequently a disruption in an individual's routine, sleep pattern, exercise, and diet. Goal striving behaviour that disrupts sleep-wake routines can lead to onset of bipolar disorder episodes as social and circadian rhythms are disrupted (Malkoff-Schwartz *et al.*, 2000). The role of goal attainment in the onset of manic episodes has received support from research conducted by Lozano and Johnson (2001). They found that achievement-striving scores were predictive of increased manic symptoms. Furthermore, Johnson *et al.,* (2000) concluded that goal attainment life events are related to increases in manic symptoms rather than positive events.

Research findings associated with the impact of goal attainment behaviour may be understood in terms of a positive feedback loop. A positive feedback loop in individuals with bipolar disorder can lead to attempts to enhance positive mood states with increasing goal attainment behaviour, disregard of feedback from others (exacerbated by activation of anti-dependency beliefs), and the disruption of normal routines (Power, 2005).

Life events are also viewed as a precipitating factor for the onset of manic episodes. Research shows that bipolar disorder patients experience significantly more excess life events compared with control participants (e.g. Bebbington *et al.,* 1993). Hammen and Gitlen (1997) found that patients who relapsed experienced more severe life events and greater accumulated stress six months prior to an onset of an episode. Neale (1988) suggested that life events that are perceived as a threat towards self-esteem can trigger grandiose thoughts that serve to prevent underlying depressive cognitions from being activated. The activation of such thoughts can, however, result in the onset of a manic episode. The type of mood-state that follows a life event is determined in part by the

individual's emotional response (e.g. feelings of helplessness may result in a depressive episode or perceived threat to self-esteem may result in a manic episode). Therefore manic and hypomanic episodes are assumed to result from a reaction to threat towards self-esteem and helplessness as a result of the individual trying to gain control.

While there is support for the negative life event hypothesis (e.g. Winters & Neal, 1985), other research has failed to find support for this explanation. For example, Hall *et al.,* (1977) carried out a prospective study using the Schedule of Life events questionnaire. They did not find a significant difference in the number of life events experienced among a group of relapsing and non-relapsing bipolar I disorder patients. Similar results have been found by Hunt *et al.,* (1992) as they concluded that 19 percent of relapses were preceded by a life event in the month prior to the relapse. Pardoen *et al.,* (1996) also concluded that life events were not associated with relapse rates. They did, however, find that hypomanic/manic episodes were associated with an increase in marital stressors prior to relapse.

1.6.2 Interpersonal and Social Rhythm Therapy (IPSRT) approach

While significantly stressful life events have been implicated as precipitants for the onset of affective episodes it is recognised that not all episodes are predated by such occurrences (Malkoff-Schwartz, *et al*., 2000). Life events that disrupt daily routines or trigger goal striving behaviour, are therefore postulated to be potential episodic triggers (e.g. Miklowitz *et al.,* 2003). Such events are implicated with the onset of both manic and depressive episodes due to the potential for disruptions in circadian rhythms. Goodwin and Jamison (2007) proposed that the circadian system, that maintains the rhythms of physiological functioning within a 24-hour period (Jones, 2004), is a primary vulnerability factor for bipolar disorder.

A key theoretical construct that is associated with the IPSRT approach is the instability model of bipolar disorder (Goodwin & Jamison, 1990). The model purports that individuals with bipolar disorder are vulnerable to disruptions in circadian rhythms.

Within the instability model taxing life events, medication noncompliance, and social rhythm disruption are viewed as potential triggers for the onset of a manic or depressive episode. It is therefore proposed that psychosocial stressors interact with the pre-existing biological vulnerability to cause symptoms (Swartz *et al*., 2004).

1.6.3 Critique of the Cognitive Model and the Interpersonal and Social Rhythm Therapy approach

While there is supporting evidence for the explanatory value of the Cognitive Therapy model and the Interpersonal and Social Rhythm Therapy approach there are limitations associated with these approaches. For example, with reference to the Cognitive Therapy model, Power (2005) has highlighted issues involved in a single schema being able to change its content and processing features in order to have a negative or positive influence on the individual. Power (2005) also asserted that because the model is cognitively focused it inadequately attends to emotion theories. A further issue highlighted by Power (2005) includes the complexity of manic episodes and whether they can be explained by the process of goal attainment leading to the activation of positive goal attainment schemas.

While research demonstrates that a relationship exists between life events and onset of bipolar episodes, there is inadequate information regarding the specific life events that are viewed as risk factors for the onset of an episode: this may be due to idiosyncratic responses to life events and therefore the difficulty involved in weighting life events in terms of individuals' subjectively negative or positive experience of events. Further limitations in this research area include small sample sizes, lack of clarity concerning the polarity of episode experienced following a life event, and questions concerning the extrapolation of findings across the spectrum of bipolar disorder. Alloy *et al.,* (2005) also highlighted issues around the standardisation of life event measures and how this term is operationalised in the research area. Issues associated with the impact of the patients' mood on the perception of life events (e.g. as negative or positive life events) were also highlighted by the Alloy *et al.*, (2005): they assert that the majority of the

research does not control for reporting biases associated with current mood state (e.g. low mood may result in a negative view of life events which may have previously be construed as positive events).

1.7 Psychosocial risk factors

Recent life events (e.g. Hammen & Gitlen, 1997), lack of social support (Miklowitz *et al.*, 1988), high expressed emotion in families (Simoneau *et al.*, 1998), and childhood affective trauma (Etain *et al*., 2008) are factors that are recognised as contributing to the development or maintenance of manic and depressive episodes. For the purposes of the current research, risk factors concerning social support and high expressed emotion will be discussed as they are relevant to the current study. The role of recent life events was discussed in relation to the cognitive model (refer to section 1.5). For a comprehensive overview of key risk factors, refer to Alloy *et al.*'s (2005) literature review.

1.7.1 Social support

Research indicates that negative social support results in a worse outcome for bipolar disorder patients (e.g. Miklowitz *et al.*, 1988). Furthermore, poor social support and low self-esteem are predictive of longer recovery time (Johnson *et al.*, 1999, 2000). Research demonstrates that social support from significant others results in a more positive course (e.g. fewer relapses) of bipolar disorder (Alloy *et al.*, 2005). Lam *et al.,* (1999) postulated that social support results in independent positive effects on psychological well-being. They also highlight the protective aspect of social support: social support is thought to act as a buffer during stressful times. Therefore, social support itself may not be directly linked to improved psychological health but it may serve to moderate or mitigate the impact of stressful events thereby reducing the impact of stress on psychological health.

1.7.2 High expressed emotion in family interactions

Studies that focus on characteristics of family interactions conclude that high expressed emotion (EE) in parents or spouses is associated with high rates of relapse, poor

symptomatic outcomes, or both in bipolar patients (Miklowitz *et al.,* 1988). Bipolar disorder patients from high EE families have been found to have more manic symptoms compared to those with from low EE families (Simoneau *et al.*, 1998). Rosenfarb *et al.*, (2001) examined family interactions involving the individual with bipolar disorder and significant others. They concluded that family interactions that involved more critical statements towards the individual with bipolar disorder were associated with higher rates of relapse.

Due to the recognition of psychosocial factors in the maintenance of bipolar disorder several psychosocial therapies have been developed or adapted from traditional therapeutic approaches. Information relating to the main therapeutic approaches for people with bipolar disorder is presented in section 1.8.

1.8 Psychosocial treatment approaches

Several forms of psychosocial therapy have been shown to be effective adjuncts to pharmacotherapy for the treatment of bipolar disorder for example: Interpersonal and Social Rhythm Therapy (IPSRT, e.g. Frank *et al.,* 2002), Family-Focused Treatment (FFT, e.g. Simoneau *et al.*, 1999), Cognitive Behavioural Therapy (CBT, e.g. Lam *et al.,* 2000), and Psychoeducation (e.g. Colom *et al.,* 2003a). The aforementioned psychosocial interventions are discussed in the following sections.

1.8.1 Interpersonal Social Rhythms Therapy (IPSRT)

IPSRT (e.g. Frank *et al*., 2002) is derived from Interpersonal Therapy (IPT, Klerman *et al.,* 1984). It is based on the theoretical assumption that life events can serve to disrupt social rhythms and circadian rhythms thereby making a patient with bipolar disorder vulnerable to a relapse. IPSRT grew from a chronobiological model of bipolar disorder that asserts that individuals with this disorder have a genetic predisposition to circadian rhythm and sleep–wake cycle abnormalities (Frank *et al*., 2000). In line with this approach it is proposed that it is a disruption to sleep-wake cycle that may be partly responsible for the symptoms associated with bipolar disorder (Frank *et al.*, 2000).

Within this therapeutic approach the patient is taught how to monitor and stabilise their sleep-wake cycle thereby stabilising irregular social rhythm (i.e. daily and nightly routines). Additional aims include helping the patient to identify triggers that are likely to disrupt normal social rhythms, to monitor their mood state, and to monitor social interactions. Psychoeducation about bipolar disorder also features in this approach (information on psychoeducation is provided in section 1.8.4). Another therapeutic focus involves helping patients to resolve interpersonal problems, that co-existed with the most recent episode (Miklowitz & Scott, 2009), by focusing on one of four areas (i.e. grief, interpersonal role transition, role dispute, and interpersonal deficits). Issues in these areas are addressed through a range of approaches (e.g. eliciting and defining the salient problem area, supported grieving/emotional processing, and problem solving). While research in this area has been limited to date, findings demonstrate that IPSRT is an effective therapy for helping patients to maintain a euthymic mood state (e.g. Frank *et al.*, 1999, Frank *et al.*, 2007).

1.8.2 Family-Focused Therapy

In Family-Focused Therapy (FFT, Simoneau *et al.*, 1999) a therapist works with the patient and their family members to provide psychoeducation, communication training, and problem solving skills. Family members' attitudes towards bipolar disorder are also reviewed. Family members and the patient jointly work with the therapist to develop relapse prevention plans.

Collectively, research demonstrates that FFT is an effective therapy for reducing relapse rates with and without pharmacotherapy (Miklowitz & Goldstein, 1990). Long-term beneficial effects have also been observed at a two-year follow-up (Miklowitz *et al.*, 2003).

1.8.3 Cognitive Behavioural Therapy

Cognitive Behavioural Therapy (CBT) focuses on helping individuals develop skills to moderate their subjective experiences of real and perceived stressors (Beck *et al.,* 1979).

CBT for people with bipolar disorder can be delivered in a group format (e.g. Castle *et al.*, 2007) or on a one-to-one basis (e.g. Lam *et al.*, 2000). Miklowitz *et al.,* (2007) have summarised the key components of CBT for individuals with bipolar disorder as consisting of:

- psychoeducation on the course of the disorder and medication adherence,
- stress management,
- life events scheduling for reducing over-stimulation,
- cognitive restructuring,
- problem solving,
- strategies for the early detection and management of prodromal symptoms, and
- learning how to challenge negative automatic thoughts and dysfunctional beliefs.

In general, research is supportive of the benefits of CBT for individuals with bipolar disorder in relation to relapse prevention (i.e. reducing time to relapse) (e.g. Lam *et al.*, 2001, 2003; Zaretsky *et al.*, 1999). Scott *et al.,* (2006), however, did not find a beneficial effect for reducing relapse rates with this approach. They concluded that illness history may interact with the individual's response to CBT and that fewer episodes are associated with a stronger relapse prevention effect. However, a recent systematic review conducted by Lam *et al.,* (2009) found no conclusive evidence to indicate that illness history is implicated in relation to the observed benefits of CBT.

The non-significant effect observed in the Scott *et al.,* (2006) study may be associated with their research sample as participants who were acutely unwell were included in their sample. The majority of research that examines the effectiveness of CBT, for individuals with bipolar disorder, recruit euthymic participants for both the experimental and control groups. For example, a research inclusion criterion often specifies that participants need to be euthymic for a minimum period of six months (e.g. Colom *et al.*, 2009). While a non-significant effect was observed in the Scott *et al.,* (2006) study this research does provides important information into when CBT is appropriate for

individuals with bipolar disorder: the results indicate that individuals who are currently experiencing a manic or depressive episode may not be appropriate for this type of therapy and that it is more appropriate for individuals who are in remission.

1.8.4 Psychoeducation

The aim of psychoeducation is to provide theoretical and practical information to individuals (and significant others when appropriate) to help them understand and cope with the consequences of their illness, to improve medication adherence, to reduce suicide risk, and to improve social and occupational function and quality of life (Colom & Vieta, 2004); this approach therefore goes beyond increasing medication compliance. Psychoeducation is generally provided on an outpatient basis when the individual is no longer acutely unwell. It can be delivered on a one-to-one basis or in a group format.

While this approach is viewed as a foundation for more comprehensive treatment programmes (e.g. FFT and CBT), it can be offered as a stand-alone intervention. Research demonstrates that psychoeducation can improve medication adherence (e.g. Peet & Harvery, 1991), increase the individual's knowledge about their illness, and increase the length of time between episodes (e.g. Colom *et al.*, 2003).

1.8.5 Similarities between Psychoeducation, CBT, IPSRT and FFT treatment models

Although there is an emerging evidence base regarding the effectiveness of psychological interventions for individuals with bipolar disorder, there is limited evidence regarding the superiority of any particular therapy. This may be due to the considerable overlap in the treatment modalities and treatment aims. For example, these approaches all include a psychoeducation component and aim to promote routine and structure in the individual's life.

An additional shared aim of the approaches is to empower the individual by helping them learn how to take an active role in their treatment. Prodromal monitoring, which

also features in the aforementioned therapies, is a therapeutic approach that enables individuals to become actively involved in their illness management. The fundamental principles of prodromal monitoring and research evidence that examines individual's experience of prodromal symptoms is discussed in section 1.9.

1.9 Self-management and psychosocial interventions

Key aims of self-management for chronic mental health conditions include involving the individual as an active partner in their illness management, improving self-efficacy and self-esteem. Patient surveys in the United States and the United Kingdom show that individuals with chronic conditions desire both self-help and psychological treatments in addition to pharmacotherapy (Hill & Shepard, 1996; Lish *et al.,* 1994).

Prodromal monitoring (which is also known as early symptom monitoring) is an effective way to involve an individual with bipolar disorder in his or her treatment management. The goal of prodromal monitoring is to reduce the likelihood of progression to a full-blown episode. This approach was originally developed for the prevention of psychotic disorders, in particular schizophrenia (Schwannauer, 2004). It has now been adapted for use with individuals with bipolar disorder (e.g. Lam & Wong, 1997). Information relating to prodromal monitoring is discussed in the following section.

1.9.1 Prodromal monitoring for individuals with bipolar disorder

Prodromes are defined as cognitive, behavioural, or affective signs of symptoms that precede a manic or depressive episode (Lam & Wong, 2005). Prodromal symptoms are thought to result from a combination of biology, psychological make-up, and past experiences (Lam & Wong, 2005). They present during the interval between the time that symptoms are first recognised to the time when symptoms reach a maximum severity (Molnar *et al.,* 1988). Prodromes are differentiated from residual symptoms that can follow an episode (Morriss, *et al.,* 2002) and subsyndromal symptoms (e.g. symptoms that do not reach the severity of episodic symptoms). Detection and

subsequent management of prodromal symptoms can assist in preventing an episode or reducing the severity of an episode (e.g. Joyce, 1985; Perry *et al.*, 1999).

The clinical psychologist's role in prodromal monitoring work is to help the patient identify the pattern of their prodromal symptoms and to develop coping strategies to manage these symptoms. Patients are encouraged to consider their prodromal symptoms in relation to mood, cognition, and behavioural symptoms and with reference to the context in which they occur (e.g. social situations) (Lam *et al.,* 1999). The next stage involves categorising the symptoms into early, middle, and late stage with reference to their temporal presentation. The clinician then works with the patient to help them to develop ways to cope with manic and depressive prodromes. Strategies can involve cognitive and behavioural techniques, lifestyle regulation (e.g. avoiding over stimulating environment, sleep management), or seeking help and support from a significant other or mental health professional. Mood monitoring charts and self-report measures such as the Internal State Scale (ISS, Bauer *et al.,* 1991) can also help patients to identify changes in their mood state that may be indicative of prodromal symptoms. While this approach is effective it is dependent upon a patient's ability to identify prodromal symptoms. Research which has examined the extent to which individuals can identify these types of symptoms is discussed in section 1.9.2.

1.9.2 Can individuals with bipolar disorder identify manic and depressive prodromes?

In order to be able to engage in prodromal monitoring individuals need to be able to identify prodromal symptoms. Research has therefore sought to examine if individuals with this disorder can reliably identify prodromal symptoms. Jackson *et al.,* (2003) conducted a systematic review of 17 studies that examined whether individuals with bipolar can identify prodromal symptoms. A combination of retrospective studies (e.g. Joyce, 1985) and prospective studies (e.g. Altman *et al.,* 1992) were reviewed. The methodology employed in relevant research included open-ended interview approaches (e.g. Joyce, 1985; Molnar *et al.,* 1988; Lam & Wong, 1997) and checklists containing

commonly reported prodromal symptoms (e.g. Altman *et al.,* 1992; Smith & Tarrier, 1992). Jackson *et al*., (2003) concluded, on the basis of the aggregated data, that at least 80 percent of the participants could identify one or more prodromal symptoms. A study conducted by Keitner *et al.,* (1996) interviewed relatives of 45 patients and concluded that there was strong agreement between patients and relatives regarding the types of prodromal symptoms experienced by the patient. Collectively, the research findings provide support for the view that individuals with bipolar disorder can identify prodromes.

Recent research by Mantere *et al.,* (2008) provides further support for Jackson *et al*.'s (2003) findings. Their research involved 191 in-patients and out-patients who were in the acute phase of bipolar disorder at baseline. The prevalence, type, and duration of preceding prodromes were investigated using open-ended questions. They concluded that prodromes were reported by 45 percent of individuals with bipolar I disorder and 50 percent of individuals with bipolar II disorder. They did not find a difference in the type of prodromes reported by individuals with bipolar I or II disorder. It is worth noting, however, that the rate of reporting for prodromal symptoms in their sample was less than that concluded by Jackson *et al.,* (2003). Mantere *et al.,* (2008) acknowledged that participants' insight into prodromal symptoms might have been affected by the sub-acute phase experienced at the time of their interviews, which may have compromised the accurate reporting of prodromal symptoms.

1.9.3 Commomly reported manic and depressive prodromes

Research indicates that individuals report experiencing more prodromes of mania than depression (e.g. Keitner *et al.*, 1996; Lam & Wong, 1997; and Lam *et al.*, 2001). Lam *et al.,* (2001) suggested that the observed difference in rate of recall may result from difficulties experienced in discriminating depressive prodromal symptoms from residual depressive symptoms. They also postulated that depressive prodromal symptoms that are somatic and cognitive in nature might be more difficult to monitor. Manic symptoms, however, were purported by Lam *et al.,* (2001) as being more recognisable due to the

associated changes in behaviour. Table 1.1 provides a summary of common prodromal symptoms that were identified by participants in the Lam *et al.,* (2001) study. For example, Lam *et al.,* (2001). used an interview approach to ask 40 patients about their experience of prodromal symptoms at baseline and at 18-month follow-up. They found good test re-test reliability for both manic and depressive prodromes that were reported by the participants.

Table 1.1 Common mania and depressive prodromal symptoms reported by 40 bipolar patients (Lam *et al.,* 2001).

Common prodromal symptoms	
Manic prodromal symptoms	Depressive prodromal symptoms
Not interested in sleep	Loss of interest in activity of people
More goal-directed behaviour	Can't put worries or anxieties aside
Increased sociability	Interrupted sleep
Thoughts starting to race	Feeling sad or wanting to cry
Irritable	Low motivation
Increased optimism	Cannot get out of bed
Over excitable and restless	Negative thinking
Spending too much	Feeling tired
Increased self-esteem	Disinterest in food
Loss of interest in food	

A review of the above common prodromes indicates that individuals are able to recognise cognitive, affective, and behavioural prodromal symptoms. Research shows that individuals with bipolar disorder are able to report prodromal symptoms consistently.

1.9.4 Length of prodromal stage

A study conducted by Molnar *et al.,* (1988) reported that the mean number of days for mania prodromes was 20.5 (range 1 to 83). The length of depression prodromes was reported to be a mean of 11 days (range 2 to 31). Smith and Tarrier (1992) concluded that mania prodromes lasted a mean of 20.5 days with a range of 1 to 84 days. They found a mean time period of 19 days for depressive prodromes with a range of 2 to 365 days. These studies indicate a wide variation in the duration of depressive prodromal

symptoms. This may be due to the manner in which length of phase is defined in the research or due to individual-related factors.

1.9.5 Methodological issues associated with prodromal identification research

While the research indicates that individuals with bipolar disorder have the ability to report prodromal symptoms, Mantere *et al.,* (2008) and Lam and Wong (2005) have identified issues associated with this research area. Mantere *et al.,* (2008) stated that the research tends to involve small sample sizes and has generally focused on bipolar I disorder patients. Lam and Wong (2005) emphasised issues involved in individuals distinguishing between residual and prodromal symptoms. They stated that some individuals might experience difficulties distinguishing between the onset of prodromal symptoms and the end of residual symptoms.

Further to the above issues, research in this area has not examined whether there is an interaction between the individual's perception of their ability to identify manic and depressive prodromal symptoms and individual-related factors (e.g. age, gender), disorder-related factors (e.g. time since diagnosis, number of manic and depressive episodes experienced), and treatment-related factors (e.g. role of significant others, the impact of previous and current involvement with mental health services). The potential relationship between individual, disorder and treatment-related variables on an individual's ability to identify and manage prodromal symptoms will be considered in more detail in Chapter 2.

1.9.6 Summary of prodromal monitoring information

Research evidence indicates that individuals with bipolar disorder can identify both manic and depressive prodromal symptoms (e.g. Jackson *et al.*, 2003). To investigate whether prodromal monitoring is an effective approach for reducing relapse rates, a systematic review was conducted. The methodology, the results and conclusions from the review are reported in Chapter 2. The current study's research rationale, aims,

research hypotheses, and research questions were developed from the systematic review findings. This information is presented at the end of Chapter 2 in section 2.9.

2.0 A SYSTEMATIC REVIEW OF RESEARCH THAT EXAMINES THE EFFECTIVENESS OF PRODROMAL MONITORING FOR INDIVIDUALS WITH BIPOLAR DISORDER

2.1 Systematic review objectives

Traditional psychosocial treatments have been adapted for use with individuals with bipolar disorder due to the limited prophylactic nature of pharmacotherapy (Parikh *et al.,* 2007) and the role of psychosocial factors in the course of the disorder (Johnson *et al.*, 2000). Prodromal monitoring (sometimes referred to as early symptom monitoring) plays a key role in a number of the adapted psychosocial approaches (e.g. Family-Focused Treatment (FFT, e.g. Simoneau *et al.*, 1999); Cognitive Behavioural Therapy (CBT, Lam *et al.,* 2000), Interpersonal and Social Rhythm Therapy (IPSRT, Frank *et al.,* 1999), and Psychoeducation (e.g. Colom *et al.,* 2003a). Psychological interventions that include a prodromal monitoring and management component have been shown to be beneficial for relapse prevention (e.g. Gitlin *et al.,* 1995; Lam *et al.,* 2003; Morriss *et al.,* 2007; Scott *et al.,* 2001).

The key objectives of the systematic review were to:

- identify research that examined the impact of prodromal monitoring on relapse rates and psychosocial outcomes for individuals with bipolar disorder;
- review the results collectively and by intervention type (e.g. one-to-one and group-based interventions) to determine the effectiveness of prodromal monitoring; and
- examine whether potential confounding variables (e.g. therapist factors, patients' expectations of therapy, time since diagnosis, and role of social support) are considered in relation to the outcome data.

2.2 Methodology

2.2.1 Criteria for considering studies

The following inclusion and exclusion criteria were used to assess study eligibility:

Distinguishing features

- Research must *explicitly* include prodromal monitoring as a key part of the intervention package (i.e. minimum of two sessions).

Research design

- The research design must include a control group.
- The participants must be randomly allocated to either the experimental or control group.

Participants

- Male and female participants must be at least 18 years of age.
- Research that includes participants with a diagnosis of bipolar I or II disorder and a co-morbid diagnosis is viewed as relevant if other inclusion criteria is met.

Types of clinical interventions

- Research must examine the impact of prodromal monitoring for manic and depressive episodes.
- The intervention can be a one-to-one therapy or a group-based intervention.
- Treatment provided for the control group must not contain aspects that are offered to the treatment group (e.g. psychoeducation or an abridged version of psychoeducation or mood monitoring).

Key outcome measures

- Research that reports time to relapse, number of hospital admissions, number of days spent in hospital, and quality of life measures was of interest.

Type of research output

- Research published in peer reviewed journals and grey literature will be considered.

Linguistic and date range

- The studies must be reported in English.
- The research will have been published between 1970 and 2009.

2.3 The search strategy

2.3.1 The database literature search string

To increase the likelihood of obtaining a comprehensive sample of research a broad research strategy was used. The search term list was constructed by noting key identifiers and descriptors from articles that were retrieved from a search on the PsycINFO database using the key words 'bipolar disorder' and 'prodromal management'.

The following search terms were entered as a search string into the relevant databases: affective disorder OR affective psychosis OR Bipolar OR Manic depression OR Bipolar affective disorder AND (early intervention OR Cognitive behavioural therapy OR cognitive therapy OR prodromal monitoring OR relapse prevention OR family therapy OR early warning signs OR monitoring OR skills training OR self management OR education OR illness management)

2.3.2 The computerised bibliographic database searches

The structure of the key search terms was modified to suit individual data sources. The PsycINFO, EMBASE, and Ovid Medicine databases were searched.

2.4 Methods of the review

2.4.1 Selection of relevant research

The literature search was carried out in October 2009. One reviewer made initial judgements regarding the suitability of the studies. Once potentially relevant information was identified via the database searches it was copied to the Refworks Web Based Bibliographic Management Software. The following six folders were created to manage the retrieved literature: 'not relevant 1', 'not relevant 2', 'not relevant 3' 'relevant 1', 'relevant 2', and 'relevant 3'. The three stages involved in the study eligibility screening process are described in section 2.4.2.

2.4.2 The study eligibility review process

In *stage 1:* Initial relevance decisions were based on the reading of titles generated by the search strategy. Some of the research titles were clearly not relevant (e.g. Carbamazepine intoxication: The result of a concomitant treatment with olanzapine?) and were therefore moved to the 'not relevant' folder. Potentially relevant papers were moved to the 'relevant 1' folder.

In *stage 2* the abstracts of the potentially relevant research were reviewed with reference to the inclusion and exclusion criteria. Research deemed not relevant at this stage was moved to the 'not relevant 2' folder. Likewise, potentially relevant information was moved to the 'relevant 2 folder'.

In *stage 3* the full-text article of the potentially relevant research was read in relation to the inclusion and exclusion criteria. Relevant studies were then moved to the 'relevant 3' folder and non-relevant references were moved to the 'non-relevant 3' folder.

2.4.3 The inclusion of research from additional resources

The reference sections of all the relevant studies (from stage 3) were reviewed in order to identify additional potentially relevant references. The abstracts of all of the potentially relevant research were read. If the article looked to be relevant the full-text article was read to determine if it satisfied the inclusion criteria. Three additional articles were identified using this search strategy. The Bipolar Disorder Journal was hand-searched from 1999 to 2009 for potentially relevant articles. No additional references were obtained using this search strategy.

Figure 2.1 provides the results from the three stages involved in identifying relevant research. Information from the additional resources search strategy is also provided.

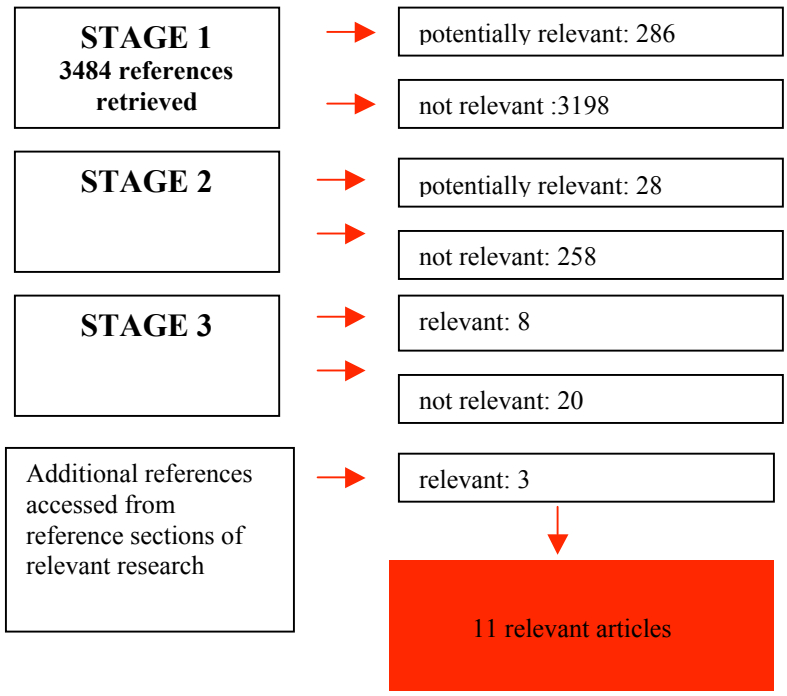

Figure 2.1 Summary of the process used to identify relevant research

2.4.4 Excluded research

Refer to Appendix 2 for explanations as to why research was excluded at *stage 3* of the study eligibility review process.

2.5 Methodological stringency

Studies designed to judge treatment should employ rigorous methodology (Chambles & Ollendick, 2001). To assess the methodological quality of the individual studies a rating form was used. Ost's (2008)[1] Psychotherapy Outcome Study Methodology Rating form was adapted for the purposes of the current systematic review by including key methodological issues associated with research in this area.

[1] Ost's rating scale was based on a scale devised by Tolin (1999) that was used in a meta-analysis that reviewed PTSD research. Tolin based his scale on Foa and Meadow's (1997, cited in Ost, 2008) guidance concerning gold standard methodology for therapy outcome studies in PTSD.

The adapted version consisted of the following 21-items: (1) clarity of sample description, (2) generalisability of the research findings for the population being studied, (3) reliability of diagnosis, (4) specificity of the outcome measures used, (5) the reliability and validity of the measures used, (6) use of blind evaluators, (7) level of assessor training, (8) how participants were assigned to treatment condition, (9) use of active and control treatments, (10) number of assessment points, (11) level of information provided on intervention, (12) number of therapists who delivered the intervention, (13) training and experience level of therapists, (14) whether checks were in place to assess treatment adherence, (15) whether therapist competence was assessed, (16) whether medication adherence was measured, (17) whether previous psychological input was measured and controlled for in the analysis, (18) equality of therapy contact hours between conditions, (19) handling of attrition from sample, (20) appropriateness of statistical analysis, and (21) whether an *a priori* power analysis was carried out. (Refer to Appendix 3 for a copy of the Methodological Rating Scale).

In order to assess the methodological quality of the research studies each item was rated as 0 for 'poor', 1 for 'fair', or 2 for 'good'. The global methodological quality of the research is discussed with reference to the following categories: low: score of 1 to 15, moderate: score of 16 to 28, or high quality: score of 29 to 42. Research-related aspects that contribute to the global methodological quality of the individual studies were also considered (see section 2.6.6 for more information).

2.6 Results

Eleven published research studies fulfilled the inclusion criteria. A data extraction form was used to obtain key information from the reviewed research (see Appendix 4 for a copy of the form). Information relating to the studies is summarised below.

2.6.1 Description of studies

The research was conducted in four countries: Spain (Colom *et al.,* 2003a, 2003b, 2009a, 2009b), Australia (Castle *et al.,* 2007), the United Kingdom (Lam *et al.,* 2000,

2003, 2005; Perry *et al.,* 1999, Scott *et al.,* 2001), and the United States (Simon *et al.,* 2005). Perry *et al.'s* study examined the role of prodromal monitoring and the patient's ability to seek support from health professionals in relation to prodromal symptoms. One study included prodromal monitoring and management as part of a more complex intervention package that used a Cognitive Behaviour Therapy (CBT) approach in a group format (Castle *et al.,* 1997). Five studies incorporated prodromal monitoring and coping strategies into a group psychoeducation approach (Colom *et al.,* 2003a, Colom *et al.,* 2003b, Colom *et al.,* 2009a, Colom *et al.*, 2009b, Simon *et al.,* 2005). The remaining four studies examined the effectiveness of prodromal monitoring as part of one-to-one CBT therapy (Lam *et al.,* 2000; 2003; 2005; Scott *et al.,* 2005).

In the Simon *et al.,* (2005) study, individuals on the waiting list were used as the control group. In the other studies, participants in the control group received treatment as usual (TAU). The studies included a follow-up period; the shortest follow-up period was three months (Castle *et al.,* 2007) and the longest follow-up period was five years (Colom *et al.,* 2009a, 2009b).

2.6.2 Methods

All of the studies used a randomised controlled trial (RCT) design. Blind assessors were used in the studies with regards to the measures that were administered to participants.

2.6.3 Participants

In total 1,110 participants took part in the 11 studies. In four of the studies (Colom *et al.*, 2003b; Lam *et al.,* 2000, 2003, 2005), the sample consisted of patients with a diagnosis of bipolar I disorder. In the Colom *et al.,* (2009b) study, the sample consisted of bipolar II disorder patients. In six of the studies (Castles *et al.,* 2007; Colom *et al.,* 2003a; 2009a; Perry *et al.,* 1999; Scott *et al.,* 2001; Simon *et al.*, 2005), patients with a diagnosis of bipolar I and II disorder were included. The participants' mean age ranged between 18 to 46 years across the studies. In all of the studies, the criteria for diagnosis included a psychiatric assessment; in general the SCID-II was used. In seven of the

studies participants with a co-morbid diagnosis were excluded (Colom *et al.,* 2003a, 2003b, 2009a, 2009b; Lam *et al.,* 2000, 2003, 2005).

2.6.4 Outcome measures

The majority of the studies defined a relapse as an episode that met the DSM-IV (1994) criteria for a manic or depressive episode. Valid and reliable measures such as the Young Mania Rating Scale (Young *et al.,* 1978) were used to measure the participants' psychiatric status and relapse status. In addition, three studies included psychosocial measures (e.g. WHO Quality of Life-BREF (WHOQOL Group, 1998) (Castle *et al.,* 2007; Lam *et al.,* 2005; Scott *et al.,* 2004).

2.6.5 Information relating to the individual studies

A summary of the main outcome findings from the relevant research studies is provided below. In addition, strengths and limitations of the individual studies are discussed. The studies are grouped in relation to the type of intervention being reviewed (e.g. one-to-one CBT and group psychoeducation). For additional information regarding the studies (i.e. methodology, statistical analyses, and the results) refer to the summary provided in Appendix 5 and the in-depth summary in Appendix 6).

2.6.5.1 Prodromal monitoring and care plans involving health professionals

Perry *et al.*'s (1999) study assessed whether teaching participants to identify prodromal symptoms significantly reduced relapse rates. The treatment group took part in a two-stage intervention that lasted for a 12-week period. A significant between-group difference was found for time to relapse for manic episodes: time to first manic relapse was 65 weeks in the treatment group and 17 weeks in the control group. However, there was no significant difference in length of manic episode between the two groups. With regard to depressive episodes, time to first depressive relapse was 21 weeks in the experimental group and 26 weeks in the control group (this difference did not reach significance level).

Key strengths of this study include the monthly assessments of the participants' illness status and the measurement of medication adherence. The sample size, however was moderate. A further limitation involves the fact that while participants were taught to identify prodromal symptoms the study does not assess if the individuals were able to manage some of the prodromal symptoms without the help of mental health professionals.

2.6.5.2 Prodromal monitoring as a feature of group delivered CBT

Castle *et al*. (1997) assessed whether a collaborative therapy package for individuals with bipolar disorder reduced rates of relapse, improved global functioning, and participants' quality of life. The results showed that more participants in the control group relapsed. While a beneficial effect of the intervention was observed the study has a number of limitations. Firstly, the sample size is small; consequently, the data did not meet statistical assumptions for some of the statistical tests used to analyse the data (i.e. logistic regression analysis). While the groups were matched on demographic and illness-related factors medication adherence was not controlled for in the analysis: therefore, the observed improvements could be due to an increase in medication adherence. While some limitations are noted, a key strength of the study is the inclusion of participants with dual-diagnosis and a diagnosis of bipolar II disorder. In addition, a 0 percent attrition rate was found: this could indicate that participants were satisfied with the intervention.

2.6.5.3 Prodromal monitoring as a feature of group psychoeducation

In Colom *et al*.'s (2003a) study participants in the experimental group received TAU and group psychoeducation that consisted of 21 sessions (90-minutes in length). The control group received TAU. During the study and at the 2-year follow-up, significantly more participants in the control group relapsed. At the 2-year follow-up significantly more participants in control group had experienced a depressive episode (significant difference) and a manic and or hypomanic relapse (non-significant difference). At the

12-month follow-up the control group had significantly more hospital admissions and had spent significantly more days in hospital.

While significant effects were observed, there was a high attrition rate in the experimental group (i.e. 26.6 percent). Key strengths of the study involve the inclusion of individuals with bipolar I and II disorder and a large sample size. Participants who were currently engaged in psychotherapy were also excluded from the study: this helps to ensure that the observed benefits are not due to other therapeutic interventions.

A further study conducted by Colom *et al.,* (2003b) used the same methodology as described for the Colom *et al.,* (2003a) study with the exception of the inclusion of only highly compliant (with regards to medication) bipolar disorder patients. This type of patient was included in order to assess whether the efficacy of psychoeducation goes beyond an improvement in medication adherence. The results showed that significantly more participants in the control group fulfilled criteria for recurrence during the treatment and follow-up phase compared to the treatment group. When the patients who relapsed were reviewed a significant difference in time to relapse was found: the treatment group had a longer period between episodes. The number of total recurrent episodes was also significantly lower in the treatment group and significantly fewer participants in the treatment group experienced a manic or mixed episode in the treatment phase. Significantly fewer participants in the treatment group experienced a manic, mixed, or depressive episode at follow-up. Furthermore, significantly more patients in the control group were hospitalised compared to patients in the treatment group; this result was also observed at follow-up.

While a number of significant between-group differences were observed, the exclusion of participants with bipolar II disorder and individuals with a dual diagnosis has an impact upon the extent to which the results can be generalised to clinical settings. The strengths and limitations discussed with reference to design features of the Colom *et al.*, (2003a) study are also relevant for this research as the same design (with the exception

of the inclusion of individuals who complied with their medication) was used for this study.

A further study by Colom *et al.,* (2009a) was carried out to assess the long-term efficacy, at 5-year follow-up, of a group psychoeducation programme. This study was an extension of an earlier study (Colom *et al.*, 2003a). The authors found a significant between-group difference for time to recurrence for both depressive and manic episodes with the control group experiencing a shorter time between episodes. When type of episode was reviewed a slightly lower effect size was observed for depressive episodes. Participants in the psychoeducation group spent significantly fewer days ill: this was significant for all types of episodes.

While the above study demonstrates the long-term efficacy of psychoeducation for individuals with bipolar disorder, the aforementioned limitations highlighted for the Colom *et al.,* (2003a) study are also relevant for this study. In addition, at the 5-year follow-up the attrition rate was high (i.e. total attrition for the study period and at follow-up).

A further study conducted by Colom *et al.,* (2009b) examined the efficacy of group psychoeducation for bipolar II disorder participants (this involved a sub-analysis of data from the Colom *et al.,* (2009a) study. No significant between-group differences in relapse rates during the intervention phase were found. At the 5-year follow-up there was a significant between group difference in relapse rates Furthermore, the control group spent significantly more days with symptoms of hypomania or depression.

The results indicated that bipolar I and II disorder patients may benefit from the same intervention. As this study used the sub-sample of data from the Colom *et al.,* (2009a) study the same limitations and strengths discussed above also apply for this study. In addition, this study involved a small sample size. Furthermore, medication adherence does not appear to have been reported or included as a covariate in the statistical

analyses; consequently, it is not possible to rule out the contribution of medication adherence to the significant findings.

In the Simon *et al.,* (2005) study participants in the treatment condition took part in a psychoeducation group. The group consisted of five weekly sessions followed by twice-monthly sessions for the duration of intervention. The treatment group had significantly lower scores over a 12-month period for mania symptoms; however, no significant between-group differences were found for time with manic symptoms. The control group spent significantly more time in hospital for manic episodes. No significant between group differences were found for depressive scores throughout the follow-up period. For individuals in the experimental group a reduction in depressive symptoms over time was observed.

This study benefits from a large sample size and the inclusion of both bipolar I and II disorder participants. Medication adherence, however, does not appear to have been included as a covariate in the relevant analyses, therefore it is difficult to determine if the observed effect on relapse rates is only due to the intervention that was delivered or if medication adherence is also relevant.

2.6.5.4 Prodromal monitoring as a feature of one-to-one CBT

In the Lam *et al.*'s (2000) study participants in the control group received TAU and multi-disciplinary team (MDT) input when required. Participants in the experimental group received TAU, MDT, and CBT (for an average of 15 sessions) that included prodromal monitoring approaches. Significantly more participants in the control group experienced manic, hypomanic, and depressed episodes in comparison to the intervention group. In addition, significantly more participants in the control group were hospitalised during the study. The experimental group also coped significantly better with manic prodromes at the 6- and 12-month assessment periods and with depressive prodromes at the 12-month period.

While significant between-group differences were observed a number of limitations are associated with this study namely the small sample size. Furthermore, the researchers did not have any control over MDT input; it is, therefore, possible that participants in the control group may have received some form of psychosocial intervention. Lastly, medication adherence was not controlled for in the statistical analyses therefore it is not possible to state that the observed effects were down to treatment alone. The two groups however, did not differ in terms of prescribed medication at baseline. While a number of limitations have been identified, this study benefited from the exclusion of participants who were receiving additional therapeutic input as this helps to clarify the effectiveness of the intervention being assessed. The study had a good follow-up period and a low attrition rate.

A further study conducted by Lam *et al.,* (2003) assessed the effectiveness of Cognitive Behavioural Therapy (CBT) compared to TAU as a means of preventing relapses and promoting social functioning. The experimental group received between 12 to 18 individual sessions over a 6-month period and two booster sessions in the second 6-month period.

Participants who received CBT had significantly fewer relapses compared with the control group; this was also found at the 12-month follow-up. The experimental group spent significantly fewer days in hospital for the total episodes experienced and for depressive episodes. The experimental group reported better coping with manic prodromal symptoms at both 6 and 12-month intervals and depressive prodromal symptoms at the 6-month interval. The authors recognised that a majority of the sample had residual depressive symptoms at baseline and stated that it may have been difficult for participants to identify when the depressive symptoms have moved to the prodromal stage. However, this explanation does not explain the significant difference observed at the 6-month interval.

Lam *et al.*'s (2003) research has a good sample size. Participants who fulfilled the criteria for substance use disorder, were, however, excluded from the sample; therefore, the extent to which the results can be extrapolated to clinical settings (due to the high rate of substance disorder found among bipolar patients) is questionable.

As a follow-up to the Lam *et al.,* (2003) study, Lam *et al.,* (2005) investigated the long-term effects of CBT. The results from the Lam *et al.,* (2005) research showed that the experimental group did significantly better in terms of cumulative relapse rates compared to the control group. This difference, however, was not observed for manic relapses. The effect of the intervention was found to be strongest during the first 12 months of the study period. This result indicates that booster sessions or maintenance therapy may be beneficial to prolong the beneficial effects of this CBT. In general, the experimental group showed better coping strategies over the last 18 months of the study and better coping with manic and depressive prodromes at the 2-year period.

While beneficial effects for CBT were found in this study, Lam *et al.,* highlighted that they did not control for the pharmacological or psychological treatment over the follow-up period. Furthermore, four participants in the control group received therapy during the follow-up period; therefore it is difficult to determine the impact of this additional support as this was not accounted for in the research design.

A study conducted by Scott *et al.,* (2001) was carried out to explore the effectiveness of Cognitive Therapy (CT) for individuals with bipolar disorder. Participants in the experimental group received a maximum of 25 sessions of one-to-one CT. The CT included relapse prevention techniques that involved prodromal monitoring and coping strategies for identified prodromal symptoms. A greater reduction in symptoms was observed in the experimental group (non-significant effect). A significant improvement in functioning was, however, found immediately following CT. A significant change in mental state was also observed as fewer people met criteria for relapse or persistent illness following CT.

The research findings can be viewed as having clinical ecological validity due to the inclusion of participants with substance disorders and personality disorders. Furthermore, the participants' views of the intervention (acceptability and potential benefits) were assessed; this enabled the participants' treatment expectations to be explored.

2.6.6 The methodological quality of the reviewed research

Information pertaining to the methodological quality of the reviewed studies is summarised below. For additional information refer to Appendix 7.

2.6.6.1 The global methodological quality of the reviewed research

Table 2.1 provides a summary of the global methodological ratings for the 11 studies.

Table 2.1 The global methodological quality ratings for the reviewed research

Study	Quality Rating
Castle *et al.* (2007)	moderate
Colom *et al.* (2003a)	moderate
Colom *et al.* (2003b)	moderate
Colom *et al.* (2009a)	moderate
Colom *et al.* (2009b)	moderate
Lam *et al.* (2000)	moderate
Lam *et al.* (2003)	high
Lam *et al.* (2005)	moderate
Perry *et al.* (1999)	moderate
Scott *et al.* (2001)	moderate
Simon *et al.* (2005)	high

As summarised above, the majority of the studies received a moderate global rating and two of the studies were categorised as being of a high methodological standard.

2.6.6.2 Information regarding the methodological quality of the studies

In addition to a global methodological rating, the quality of the research was reviewed in relation to key methodological information. This information is summarised below.

2.6.6.2.1 Sample information

The extent to which the research sample was representative of clinical samples is questionable. This is largely due to the exclusion of participants with an axis l disorder, and a substance use disorder. There is a high rate of co-morbidity among individuals with a diagnosis of bipolar disorder (e.g. McElroy *et al.*, 2001). It is therefore questionable if research findings from studies that exclude research individuals with co-morbid diagnoses can be extrapolated to clinical settings.

2.6.6.2.2 Design-related issues

Ten of the 11 studies included a follow-up period of at least one year. All of the studies used random allocation to assign participants to the control or experimental groups. An active treatment in comparison to either a waiting list group or a TAU group was also used; however, none of the research compared the intervention with another previously empirically documented active treatment. In only two of the 11 studies (Lam *et al.*, 2003; Simon *et al.*, 2005) assessor training and checks were used during the intervention to ensure treatment fidelity. Therefore, it is not possible to conclude that in the remaining studies the packages were being delivered in a standardised manner.

2.6.6.2.3 Therapist factors

In the Lam *et al.,* (2000, 2003, and 2005) and Simon *et al.,* (2005) studies, the intervention was delivered by three or more therapists: the inclusion of three or more therapists helps to reduce the likelihood that the observed effect of the intervention is due to therapist-related factors (e.g. experience, gender, therapeutic alliance). The majority of the studies used therapists with considerable clinical experience. However, with the exception of the Lam *et al.,* (2003, 2005) studies, therapist competence was not

monitored throughout the research study. Furthermore, none of the studies assessed for potential impact of therapist-factors in relation to the research outcomes.

2.6.6.2.4 Confounding variables

Previous psychosocial input was not measured in the studies; therefore, it is not possible to assess if previous psychosocial interventions had an impact upon current functioning. Five of the studies (Castle *et al.*, 2007; Colom *et al.*, 2003a, 2003b, 2009a, 2009b; Scott *et al.*, 2001) addressed issues associated with equal contact hours between the control and experimental groups. The provision of equal contact hours between conditions reduces the likelihood that the observed treatment effect was due to increased contact with mental health professionals. In six of the studies, however, equal contact time for the two groups was not provided; therefore it is not possible to state that the observed effect was due to the intervention alone.

2.6.6.2.5 Statistical issues

With the exception of the Castle *et al.,* (2007) study appropriate statistical tests were used to analyse the data. The majority of the studies (with the exception of Castle *et al.*, 2007 and Simon *et al.*, 2005) used intent-to-treat analysis to manage attrition issues.

To summarise, while methodological limitations have been identified the studies were viewed as being of at least moderate methodological quality. The research findings are considered collectively in section 2.7.

2.7 Discussion

The research findings are considered collectively in order to determine the extent to which prodromal monitoring is effective for reducing relapse rates for individuals with bipolar disorder. Strengths and limitations of the research area also considered.

2.7.1 Summary of the research results

While methodological limitations were identified, in general the research demonstrates the efficacy of psychosocial approaches that utilise a prodromal monitoring and management component for a reduction in relapse rates and hospital admissions for manic and depressive episodes. Significant effects were found for both one-to-one and group-based interventions. Two of the studies, however, did not find a significant effect of intervention type with depressive episodes (Castle, *et al.,* 2007; Perry *et al.*, 1999). This may be due to the difficulties individuals experience in separating subsyndromal depressive symptoms from prodromal symptoms. A difference, in terms of the polarity of symptoms, is also observed in research that examines individuals' ability to identify manic and prodromal symptoms: research indicates that participants identify more manic than depressive symptoms (e.g. Keitner *et al.*, 1996; Lam & Wong, 1997; and Lam *et al.*, 2001).

An alternative explanation for the observed non-significant effect in the Castle *et al.*, (2007) and Perry *et al.*, (1999) studies could involve the type of intervention used. For example, research that utilised a one-to-one therapeutic CBT approach (e.g. Lam *et al.*, 2003) found a significant decrease in the number of depressive episodes experienced by participants in the intervention group. It may be that a group-based CBT is not in-depth or individualised enough to enable participants to learn how to distinguish between subsyndromal and prodromal depressive symptoms. In the Perry *et al.,* (1999) study, participants were taught how to identify prodromal symptoms but not how to manage them without the assistance of mental health professionals. It is possible that depressive prodromes become more recognisable once participants have experience in managing them, as individuals are then able to separate prodromal symptoms from subsyndromal symptoms.

Long-term follow up not only provides insight into the enduring effects of this therapeutic approach but also enables the participants to practise CBT strategies and techniques. The Scott *et al.*, (2005) study indicated that while the experimental group

had fewer relapses than the control group there was a slight decline in effectiveness of CBT at the 12-month follow-up. Lam *et al.,* (2005) found a similar result. These findings may indicate the need for booster sessions following the intervention period. However, Colom *et al.*'*s* (2009b) research (that involved bipolar II disorder participants) found no effect on relapse rates following the intervention but did find a significant effect at the five-year follow-up. This study indicates that participants may become more skilled with CBT strategies and techniques over time. It is difficult to determine why the results from the Colom *et al*., (2009b) study are in conflict with Lam *et al*., (2005) and Scott *et al*.'s (2005) findings; the results may be due to individual differences associated with the research samples.

2.7.2 The methodological quality of the reviewed research

While some methodological limitations have been identified, overall the research was of a moderate methodological standard. A three-way median split approach was used to categorise the global methodological quality of the reviewed research. While Ost's methodological rating form was not designed to be used in this manner, categorising the research provides a way of identifying high, moderate, and low quality research. Therefore, this approach can be viewed as beneficial as it provides a way of determining the global methodological quality of the individual studies. Categorising the research in this manner should, however, be viewed with caution as it does not enable individual methodological items to be weighted. The categorisation of the research should therefore be considered in relation to the individual items on the rating form.

2.7.3 Methodological limitations associated with the research area

With the exception of the Perry *et al.,* (1999) study, the reviewed research included prodromal monitoring and coping strategies as part of a larger intervention package: none of the studies looked at components of therapy separately or asked the participant which skills and strategies they found most effective. While it is not possible to conclude that prodromal monitoring approaches are solely responsible for the observed positive change in relapse rates, it is realistic to assume that therapeutic processes described in

the research papers would mirror clinical practice and thus prodromal monitoring is unlikely to be introduced and taught to a client in isolation from associated CBT techniques and strategies.

2.7.4 Issues associated with potentially confounding variables

The participants' prior experience of psychological therapies was also not considered in the research. A previous positive therapeutic experience may serve to motivate the individual, whereas a negative experience may effect outcome expectations and subsequent motivation to engage in therapy. Whether or not participants were receiving additional support (e.g. CPN, attending classes, help from significant others) was also not considered. The potential impact of additional support and participant's previous experience of therapy should be assessed and used as a covariate in the statistical analyses to assess the impact of prior psychosocial interventions on current functioning and control for the impact of such factors on research outcomes.

2.7.5 What helps individuals with bipolar disorder to identify and manage prodromes?

When prodromal monitoring is considered within the context of both disorder management and recovery, aspects that help individuals to believe that they can take an active role in their treatment become important factors; a sense of mastery over symptoms helps individuals believe that they can be an active agent in their treatment (Muesser *et al.,* 2004). While the research has collectively demonstrated the effectiveness of prodromal monitoring for reducing time to relapse it has not explored which factors help individuals to identify and manage prodromal symptoms. For example, the potential impact of disorder-related variables (e.g. consistency of symptoms, time since diagnosis, and number of episodes experienced in relation to the outcome measures or participant's engagement with the interventions) on participants' ability to identify and manage prodromal symptoms were not considered in the reviewed research. Therefore, it is not possible to conclude whether or not such factors have an impact on the effectiveness of the psychosocial interventions under investigation.

Information relating to the benefits of considering the role of social support and general self-efficacy with reference to prodromal monitoring is presented below.

While some of the studies provided information on aspects such as marital status (e.g. Castle *et al.*, 2007, Colom *et al.*, 2003) the role of social support was not considered in the reviewed research. As discussed in chapter 1 section 1.7.1 research indicates that social support leads to a more positive course of bipolar disorder (e.g. Johnson *et al.,* 2000), whereas low level and less adequate support are associated with poorer symptomatic outcomes (e.g. Kulhara *et al.*, 1999).

To date, research in this area has not examined the relationship between either social support from significant others and or psychosocial input from mental health professionals with specific attention to the impact this has on an individual's perception of his or her ability to monitor and manage prodromal symptoms. As social support is associated with a more positive course of bipolar disorder it is helpful to explore the role this type of support provides in helping individuals to identify and manage prodromal symptoms.

Self-efficacy is a construct that has an impact upon health practices as well as adaptation to illness and treatment as it reflects an optimistic self-belief (Bandura, 1986) and refers to personal action control and agency (Schwarzer *et al.*, 1999). Self-efficacy is defined as 'people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives.' (Bandura, 1994, p.71) While self-efficacy can be viewed as domain-specific, it can also be viewed as relating to a broad and stable sense of belief in the ability to cope with a variety of difficult situations such as life events and management of prodromal symptoms (Schwarzer, 1994). Schwarzer and Jerusalem (1995) assert that general self-efficacy is positively related to optimism, proactive coping, and self-regulation. It would therefore appear that general self-efficacy is an important measure to consider in relation to prodromal monitoring as this approach involves individuals taking an active role in the management of their

disorder. Furthermore, general self-efficacy is open to introspection via the use of questionnaires (e.g. the General Self-Efficacy Questionnaire, Jerusalem & Schwarzer, 1995). To date, general self-efficacy has not been considered in relation to self-management of bipolar disorder.

2.7.6 Conclusion

In conclusion, although research limitations have been identified, the research collectively demonstrates the effectiveness of psychosocial interventions that utilise prodromal monitoring and management approaches for reducing relapse rates. In addition to reviewing research that examines the impact of prodromal monitoring approaches, this systematic review has served to highlight research gaps with reference to aspects that have not been considered in relation to prodromal monitoring. This issue is further explored in section 2.8.

2.8 The thesis research hypotheses and research questions

Research to date has examined the relationship between prodromal monitoring in relation to outcome measures such as time-to-relapse, hospitalisation, severity, length of episode, and quality of life measures. The research has not investigated whether certain factors serve to increase or decrease individuals' perceptions that they are able to identify and manage manic and depressive prodromal symptoms thereby increasing their confidence as active agents in the management of their disorder.

The current research aimed to identify relevant factors that have an impact upon individuals' perception that they can identify and manage manic and depressive prodromal symptoms. By investigating this issue, prodromal monitoring can become a more specified approach that considers other relevant therapeutic factors. A quantitative exploratory research approach was used to investigate the impact of individual (i.e. self-efficacy, gender, age), treatment (psychosocial input, role of significant others in helping to mange bipolar disorder), and disorder-related factors (i.e. time since diagnosis, number of episodes experienced, consistency of prodromal symptoms, and current mood

state) on individuals' perceptions of their ability to identify and manage prodromal symptoms.

The following research question was used to develop the research hypotheses:
How are individual-related, disorder-related, and treatment-related factors associated with participants' perception of their ability to identify and manage manic and depressive prodromal symptoms?

Hypothesis 1:

Research hypothesis: General self-efficacy will be positively associated with participants' perception of their ability to identify and manage manic and depressive prodromal symptoms. (one-tailed)

Hypothesis 2:

Research hypothesis: Social support, in relation to help from significant others in managing bipolar disorder, will be positively associated with the participants' view of their ability to identify and manage prodromal symptoms. (one-tailed)

Hypothesis 3:

Research hypothesis: Previous and current psychosocial input will be positively associated with the participants' perception of their ability to identify and manage prodromal symptoms. (one-tailed)

The following exploratory questions were also considered in relation to the research findings:

i) Are the following factors associated with participants' perception of their ability to identify and manage prodromal symptoms: time since diagnosis, gender, age, number of episodes experienced, and current mood state?

ii) Does the consistency of prodromal symptoms (across episodes) have an impact on participants' perception of their ability to identify and manage prodromal symptoms?

iii) Does the ability to identify prodromal symptoms when they first present have an impact on participants' perception of their ability to identify and manage prodromal symptoms?

iv) Is the polarity of the prodromal symptom associated with the participants' perception of their ability to identify and manage manic and depressive prodromal symptoms?

v) Are types of prodromal symptoms (i.e. cognitive, affective, and behavioural) associated with the participants' perception of their ability to identify and manage manic and depressive prodromal symptoms?

Information regarding the methodology that was used to examine the above hypotheses and research questions is discussed in the following chapter.

3.0 METHODOLOGY

3.1 Design

This exploratory study utilised a cross-sectional quantitative research design to investigate the research hypotheses and research questions. The data were obtained via the administration of four self-report measures. An additional questionnaire (the Prodromal Experience Questionnaire) was administered to a sub-sample of the participants. Information regarding the inclusion of this questionnaire is discussed in section 3.4.2.

Hypothesis 1: General self-efficacy will be positively associated with participants' perception of their ability to identify and manage manic and depressive prodromal symptoms. (one-tailed)

An independent design was used to allow the general self-efficacy scores to be examined in relation to the participants' perception of their ability to identify and manage manic and depressive prodromal symptoms (i.e. able to, sometimes able to, not able to). The independent variable was the participants' perception of their ability to identify and manage prodromal symptoms and the dependent variable was the participants' general self-efficacy score.

Hypothesis 2: Social support, in relation to help from significant others in managing bipolar disorder, will be positively associated with the participants' view of their ability to identify and manage prodromal symptoms. (one-tailed)

This hypothesis was tested using a between-participants design to determine whether help from significant others is associated with the participants' perception of their ability to identify and manage prodromal symptoms. The independent variable was whether or not a significant other provided support and the dependent variable was the participants' perception of their ability to identify and manage prodromal symptoms.

Hypothesis 3: Previous and current psychosocial input will be positively associated with the participants' perception of their ability to identify and manage prodromal symptoms.

(one-tailed) was tested using a correlational design in order to reveal whether there is an association between participants' perception of their ability to identify and manage prodromes in relation to the level of psychosocial input they have received.

The research questions (refer to chapter 2, section 2.8) were explored through a combination of correlational and between-participant designs. The design was dependent on the type of data (e.g. continuous, categorical) that was being analysed

3.2 Power analysis

To date, research has not examined the relationship between individual, disorder, and treatment-related variables and perceptions of ability to identify and manage prodromal symptoms for people with bipolar disorder. Therefore it was not possible to determine a suitable effect size for the current research, on the basis of empirical findings from previous studies. A decision was therefore made to establish the number of participants required to achieve a medium effect size of .80 (Cohen, 1992). The data were analysed through a series of preliminary and primary analyses. Information relating to the preliminary analysis is firstly presented, with reference required sample size, based on power calculations. Information regarding the primary analysis is then discussed.

3.2.1 Preliminary Analysis

Hypothesis 1 investigated the impact of general self-efficacy scores on participants' ability to identify and manage prodromal symptoms. This data was explored through the use of a one-way ANOVA. With reference to this statistical test, Cohen (1992) states that in order to achieve a medium effect size, (at a significance level of 0.05) a minimum sample of 52 participants is required.

Hypothesis 2 examined whether help from significant others in managing bipolar disorder was positively associated with the participants' view of their ability to identify and manage prodromal symptoms. To test this hypothesis a 2 x 3 Pearson chi-square statistical test was used. Cohen (1992) stated that in order to achieve a medium effect

size, (at a significance level of 0.05) using this test of association, a minimum of 107 participants is required.

Hypothesis 3 tested whether there is a relationship between level of psychosocial input and the participants' perception of their ability to identify and manage prodromal symptoms. The Spearman's rho test was used to test whether a relationship existed between these variables. Information provided by Cohen (1992) indicates that in order to achieve a medium effect size (at a significance level of 0.05) using this test, a minimum of 85 participants is required.

3.2.2 Primary Analysis

The primary analysis was conducted in order to assess the overall contribution of relevant variables (as determined by the preliminary analyses) to the participants' ability to identify and manage prodromal symptoms. The ordinal logistic regression analysis test was chosen as the most appropriate statistical technique to use in the primary analyses. Four ordinal logistic regression tests were carried out to explore factors associated with the participants' ability to:

- identify manic prodromes,
- identify depressive prodromes,
- manage manic prodromes,
- manage depressive prodromes.

Predictor variables identified as being significantly related to the dependent variables (due to results from the preliminary analysis) were entered into each regression model. The number of predictor variables entered ranged from two to five. Therefore, an *a priori* sample size was considered in relation to five predictor variables for a regression analysis.

Several methods exist for establishing the number of participants required in a regression analysis. Cohen (1992) states that in order to achieve a medium effect size, (at a significance level of 0.05), with five predictor variables, a sample of 91 participants is required. Harris (1985, cited in Dancey & Reidy, 2004) proposes the following equation to calculate the recommended sample size for a regression analysis:

N ≥ 50 + m (**m** = the number of predictor variables). There are five predictor variables in the present study; therefore, based on Harris' equation, a total of 55 participants would be required. When considering assumptions associated with regression analysis, Long and Freese (2006) recommend a minimum sample of 100 participants regardless of the number of estimated parameters. For the ordinal regression analysis it was decided that it would be best to have a minimum of 100 participants in the study, as this is in accordance with the aforementioned figures provided by Cohen (1992) and Long and Freese (2006). When the required sample size was reviewed in relation to all of the tests being carried out it was determined that it would be best to have a minimum of 107 participants.

3.3 Participants

Potential participants were recruited through adult Community Mental Health Teams (CMHTs), Mood Stabiliser Clinics, and voluntary agency mental health services within the geographical area of Forth Valley. Participants were also recruited from across the country via the Bipolar Fellowship of Scotland.

With reference to the participants recruited via the CMHTs and the Mood Stabiliser Clinics, key workers and psychiatrists referred potential participants if exclusion and inclusion criteria (summarised in Table 3.1) were met.

Table 3.1. Inclusion and exclusion criteria for participation in the research

Exclusion Criteria	Inclusion Criteria
Individuals who are inpatients	Fluent in English
Individuals who have a learning disability	A diagnosis of bipolar I or II disorder
Individuals who are unable to provide informed consent	Minimum age of 18 years old
	Individuals involved with NHS services, mental health services within the geographical area of Forth Valley, or the Bipolar Fellowship self-help groups

The research sample consisted of 101 participants with a diagnosis of bipolar disorder. Demographic and bipolar disorder-related information pertaining to the research sample are presented in the Chapter 4 section 4.2.1.

3.4 Measures

All of the participants were asked to complete four questionnaires. As previously noted, a sub-sample completed a further questionnaire. The five questionnaires are described below.

3.4.1 The Demographic Questionnaire

The Demographic Questionnaire (Appendix 8) was designed for the purposes of this study. It was administered to participants in order to obtain demographic, clinical, disorder, and prodromal-related information. Participants were also asked to provide information on whether a significant other helped them to manage prodromal symptoms.

The questions concerning the participants' experience of prodromal symptoms were prefaced with a description of prodromal symptoms and a list of common manic and depressive prodromes. The questionnaire took an average of 10 minutes to complete.

3.4.2 The Prodromal Experience Questionnaire

The retrospective Prodromal Experience Questionnaire was developed for the current study in order to obtain information about participants' experiences of prodromal symptoms (Appendix 9). As stated above, the questions concerned with the participants' experience of prodromal symptoms were prefaced with a list of common manic and depressive prodromal symptoms. The researcher noted that some of the participants were using the list to identify, through the use of a check mark, the prodromes that they have experienced in the course of their disorder. Therefore the decision was made to adapt the list of common prodromes into a questionnaire to collect systematic information regarding future participants' experience of prodromal symptoms (i.e. prodromes experienced, easily identified, consistently experienced, and viewed as manageable). The addition of this questionnaire enabled information on different types of prodromes (i.e. cognitive, affective, and behavioural) to be collected and examined in relation to individual, disorder, and treatment-related variables.

A sub-sample of 48 participants (from the original sample) completed this questionnaire. The questionnaire contained a list of 18 commonly experienced manic and depressive prodromes in the form of a checklist. Information provided by three studies, in which participants were asked to either spontaneously recall prodromes (Lam & Wong, 1997; Molnar *et al.*, 1988) or identify prodromes they have experienced via a checklist approach (Smith & Tarrier, 1992), was used to inform which prodromes should be included in the checklist. The prodromes can be categorised into cognitive, affective, and behavioural symptoms (refer to Appendix 10 for categorisation of the prodromes by type).

For each of the listed prodromal symptoms the participants were asked to indicate (by using a check mark) if they:

- experienced the prodromal symptom
- were able to identify the prodromal symptom when it first presented
- always experienced the prodromal symptom
- believed they were able to manage the prodromal symptom

The questionnaire took an average of five minutes to complete.

3.4.3. The General Self-Efficacy Scale

The General Self-Efficacy Scale (GSES, Jerusalem & Schwarzer, 1995) (Appendix 11) was administered to participants in order to gain a numerical measure of their general self-efficacy. The construct of perceived self-efficacy reflects an optimistic self-belief (Schwarzer, 1992). This measure was therefore administered to the participants to assess if self-belief has an impact upon their perception of their ability to identify and manage prodromal symptoms.

The GSES is a 10-item questionnaire that takes approximately five minutes to complete. It is designed for use with adults and adolescents. It was originally developed in German but has been translated into 28 languages, including English (Schwarzer & Jerusalemm 1995). The ten items are designed to measure how individuals cope with a range of demands in life. Each item refers to successful coping and implies an internal-stable attribution of success.

Participants were asked to read one statement at a time and consider the extent to which each statement applied to them. They were instructed to respond using the following numerical response format: 1 for not at all true, 2 for hardly true, 3 for moderately true, and 4 for exactly true. Participants' responses to the 10 questions were totalled to get an

aggregate score within a range of 10 to 40. Higher scores on the measure indicate higher levels of general self-efficacy.

Research indicates that the GSES typically yields internal consistencies between $\alpha = .75$ and .91 (e.g. Schwarzer *et al.*, 1999). While, to date the measure has not been used with individuals with bipolar disorder it has been used in a number of studies involving long-term psychiatric patients (e.g. Ritsner, 2006; Vauth *et al.*, 2007).

3.4.4 Internal State Scale

The Internal State Scale (ISS, Bauer *et al.*, 1991) was used to obtain a measure of the participants' current mood state. The ISS is a 16-item self-assessment tool for individuals with bipolar disorder (Appendix 12). The ISS was designed to provide a simple mood self-report for both manic and depressive symptoms. The items include a range of symptoms that describe mania and depression and represent four subscales: activation level, sense of wellbeing, depression, and characteristics that may occur in either affective state. The subscales discriminate among mania, depression, mixed, and euthymic mood states.

Participants are instructed to respond to the 16 statements by using an X to indicate at which point on a 100mm line best describes how they have felt over the past 24 hours. The 0 anchor point is "not at all, rarely". The 100 anchor point is 'very much so, much of the time. For example:

	Not at all Rarely	Very much so Much of the time
1. Today my mood is changeable	——————X——————	

Responses are then summed to provide the subscale score. An ISS scoring algorithm (provided by the authors) was used to classify the respondent's mood state. The scoring

algorithm uses the activation subscale and the well-being subscale scores to classify the respondents' mood state as: (hypo)manic, mixed state, euthymic, or depressed.

The activation subscale correlates highly (r =.60) with the Young Mania Rating Scale (Young *et al.,* 1978) and the Depression Index correlates with the Hamilton Depression Rating Scale (Hamilton, 1967) (Bauer *et al*., 1991). The ISS also discriminates among patients with manic symptoms and controls (Bauer *et al.*, 1991). Further research has also demonstrated that the ISS can discriminate mood states for both in-patients and out-patients (Bauer *et al.*, 1999) and community samples (Bauer *et al.*, 2000).

3.4.5 The Significant Others Scale

To assess the participant's perception of the role of significant others in their social network the Role of Significant Others Scale (SOS, Power *et al.*, 1988) (Appendix 13) was administered to the participants. The SOS measures different sources of social support that may be provided by a number of significant relationships within an individual's social network. The scale distinguishes between structural and functional aspects of support and enables a measure of ideal and actual support to be determined.

Participants are asked to list up to seven people whom they view as important people in their life. For each person they are instructed to answer eight questions designed to assess both structural and functional support provided by the significant other. Participants respond by circling a number on a seven-point Likert scale that represents the following responses: never, sometimes, or always receive this type of support. In addition, participants are asked to indicate their ideal level of support for each nominated person, and for the structural and functional aspects of support they are considering.

The SOS has demonstrated good test re-test reliability over a 6-month period (Power *et al.*, 1988). The SOS was not developed using a clinical population as a sample of female members of the Open University Psychology Society were recruited to provide

information that was used to develop the SOS. The SOS has however been used in a number of subsequent research studies that have involved long-term psychiatric patients (e.g. Cresswell *et al.*, 1992).

3.5 Procedure

As previously stated the participants were recruited through (i) CMHTs and Mood Stabiliser Clinic referrals, (ii) voluntary agencies mental health services, and (iii) the Bipolar Fellowship of Scotland. Information pertaining to the procedure used in each recruitment source is described below.

3.5.1 CMHTs and Mood Stabiliser Clinics

The researcher met with key workers, psychiatrists, and managers in the CMHTs and Mood Stabiliser Clinics in order to discuss the research project with specific reference to the research rationale, aims, ethical issues, and participant inclusion and exclusion criteria. An information sheet was given to the referrers (Appendix 14) that summarised the information discussed at the meeting.

The referrers were asked to discuss the research with suitable patients if they believed they met the inclusion criteria. In addition to discussing the research with the patient they also received an information sheet (Appendix 15) that included information on what participation in the research would involve planned use of the research findings, and contact details for the researcher and an independent researcher if they wished to discuss the study in more detail. If the patient expressed interest in taking part in the study the referrer then passed their contact details on to the researcher.

All potential participants were given a minimum of 48 hours to consider taking part in the study, during which time they were able to contact the researcher to discuss the study in more detail if they had any questions. After this time, the researcher called the potential participants to discuss taking part in the study. If an individual was interested

in taking part in the study a suitable time and place was arranged (e.g. NHS setting or a community drop-in centre) for the participant to complete the questionnaires.

Several participants stated that they wanted to complete the questionnaires at home. When this occurred the researcher posted a questionnaire pack with a self-addressed return envelope to the participant. The researcher then contacted the participant once they had received the questionnaire to discuss the questionnaires in more detail and to check if participants had any questions. The participants were advised to contact the researcher if they found any aspect of the questionnaires distressing or anxiety-provoking; they were also advised that if this were to occur they should stop filling out the questionnaires.

3.5.2 Voluntary agencies

In order to recruit participants from voluntary agencies the researcher attended meetings that involved staff and individuals who used the drop-in facilities to discuss the research. As described above – information was provided about the inclusion and exclusion criteria and an information sheet was given to potential participants. Following the meeting staff took a note of individuals who were interested in taking part in the research. These individuals were contacted following a period of 48 hours and a time and date was arranged for them to complete the questionnaires at the respective drop-in facilities.

3.5.3 The Bipolar Fellowship of Scotland

Individuals recruited via the Bipolar Fellowship self-help groups were informed of the research and given the information sheet in advance of the researcher attending the group meetings by the central office. During the meeting they were asked if they would like to take part in the study. Individuals who agreed to take part in the study completed the questionnaire either during the meeting or at home. As stated above, participants who chose to take the questionnaire home were informed that they could contact the researcher to discuss the questionnaires and the research study.

The order of the questionnaires was counterbalanced with 50 percent of the participants completing the questionnaires in order 1, and 50 percent completing the questionnaires in the reverse order. Table 3.2 provides a summary of the order of the questionnaires.

Table 3.2 Order (1) that the questionnaires were given to participants

Order of the Distribution of the Questionnaires
Demographic Questionnaire
Prodromal Experience Questionnaire (sub-sample)
General Self-Efficacy Scale (Schwarzer & Jerusalem,1995)
The Internal State Scale (Bauer *et al.*, 1991)
Significant Others Scale (Power *et al.*, 1988)

3.6 Participant confidentiality

All of the questionnaires were anonymously completed to ensure participant confidentiality. The completed questionnaires and the consent forms were kept in a locked filing cabinet in NHS Forth Valley Adult Clinical Psychology Department. No identifying information was included in any database or stored electronically.

3.7 Ethical issues

Individuals with bipolar disorder are a potentially vulnerable group due to the relapsing nature of their condition and the fact that individuals may experience subsyndromal symptoms and cognitive and emotional impairment when remitted. Ethical issues, in line with British Psychological Society Code of Conduct, Ethical Principles and Guidelines (British Psychological Society, 1995), were adhered to throughout the study in order to reduce potential burden to the participants. Furthermore, the inclusion and exclusion criteria were designed to highlight that acutely unwell individuals were not suitable to take part in the study due to vulnerabilities (e.g. issues around ability to consent to research participation) associated with being unwell.

Ethical issues were considered when selecting the research measures. A key factor in determining which tests would be used involved ensuring that the measures would not cause the participants undue stress. An additional consideration involved choosing

measures that would be informative yet quick to administer and complete. Some of the questions required participants to reflect on their experiences of having this disorder. Participants were informed that they did not have to answer any questions that they found too anxiety-provoking or distressing.

If a participant became upset during the study the researcher would refer them to the appropriate service. As General Practioners (GPs) are often the first point of contact for distressed patients they were informed by way of a standard letter (see Appendix 16) that their patient was taking part in a study. Participants were given the researcher's contact details in case they wished to discuss any aspect of the study prior to or following the questionnaires being completed. Each participant completed a consent form prior to taking part in the study (see Appendix 17).

3.8 Ethical approval

The Fife, Forth Valley and Tayside Research Ethics Committee reviewed the proposal for this study. After reviewing the proposal, the committee granted approval for this research to be carried out (Appendix 18). Approval was also granted from the University of Edinburgh Clinical Psychology Ethics Committee (Appendix 19) and the Research and Development (R&D) office in NHS Forth Valley (Appendix 20).

4.0 RESULTS

4.1 Overview of the preliminary analyses

The data were analysed using the Predictive Analytical Software version 17 for Windows. The sample characterised were explored to provide additional information about the research sample. The data was then examined in relation to the research hypotheses (refer to section 2.7). In addition, exploratory analyses were conducted in order to investigate the relationship between the individual, disorder, and treatment related variables (refer to the research questions section 2.7).

The strategy of analyses and the results for each stage is provided below.

4.2 Strategy of analysis: The sample characteristics

Descriptive and inferential statistical tests were used to investigate if there were significant differences between the three recruitment sources (i.e. Bipolar Fellowship, psychiatric and community referrals) with reference to demographic (e.g. age, gender) and clinical variables (e.g. diagnosis, number of episodes experienced). Statistical tests were selected based on the type of data being analysed. Tests of normality of distribution and homogeneity of variance were used to evaluate the data against assumptions for parametric tests (Dancey & Reidy, 2004). The Kolmogorov-Smirnov test was used to determine if the distribution of scores differed significantly from normality and the Levene's test was used to test for equality of variance. When the data did not adhere to the assumptions of parametric tests, the non-parametric equivalent test was used. When non-parametric tests were conducted the parametric equivalent test was also carried out to establish if the results were in line with the non-parametric finding. Unless otherwise specified the results from the parametric tests were in line with the non-parametric results.

4.2.1 Results: The sample characteristics

The data were collected from 101 participants: 58 participants (57.4 percent) were female. Seven participants who initially agreed to take part in the research, withdrew from the study (these individuals are not included in the total sample figure). The main reason for withdrawing from the research was not having time to participate.

Ninety-five percent of the sample reported that they were prescribed and taking medication for bipolar disorder. The researcher did not carry out medication adherence checks. Eighty-nine percent of the sample stated they had contact with a psychiatrist regarding management of their disorder. Demographic and clinical variables for the three referral sources are summarised in Table 4.1.

Table 4.1 Summary of participant demographic and clinical variables

	Bipolar Fellowship ($N = 70$)		Community ($N = 7$)		Psychiatric ($N = 24$)	
	M (SD)	Range	*M* (SD)	Range	*M* (SD)	Range
Age	46.33 (11.06)	24-72 yrs	42.71 (7.80)	28-50 yrs	44.57 (8.76)	25-58 yrs
No. of manic episodes	17.88 (40.01)	1-216	3.00 (2.31)	1-5	22.37 (67.42)	1-300
No. of depressive episodes	18.53 (29.12)	1-144	3.99 (1.73)	2-5	47.89 (115.8)	1-500
Time since diagnosis	12.41 (9.86)	1-40 yrs	11.32 (8.36)	1-30 yrs	6.43 (5.19)	1-40 yrs
	N	%	*N*	%	*N*	%
Male	28	34	1	14	13	50
Female	42	66	6	86	11	46
BPI	44	63	2	28.5	9	37
BPII	6	9	1	14	5	21
RC	5	7	2	29	5	21
Unknown	14	20	2	29	5	21

(BPI = bipolar I disorder, BPII = bipolar II disorder, RC = rapid cycling specifier)

There were no significant between-group differences with reference to clinical and demographic-related variables. (Refer to Appendix 21 section 2 for the statistical test results).

4.3 Strategy of analysis: The preliminary analyses

4.3.1 Preliminary analyses and the research hypotheses

The procedure described in section 4.2 was used to determine whether a parametric or non-parametric test was used to explore the data. Cohen's (1998) guidance regarding the size of correlations (i.e. small = < 0.3, moderate = 0.3 to 0.5, and large = > 0.5) was used to determine the size of significant associations. The preliminary analysis was conducted in order to test the following hypotheses:

Hypothesis 1:

General self-efficacy will be positively associated with participants' perception of their ability to identify and manage manic and depressive prodromal symptoms. (one-tailed) This hypothesis was investigated through the use of a one-way ANOVA.

Hypothesis 2:

Social support, in relation to help from significant others in managing bipolar disorder, will be positively associated with the participants' view of their ability to identify and manage prodromal symptoms. (one-tailed) This hypothesis was explored through the use of the 2 x 3 Pearson chi-square test.

Hypothesis 3:

Previous and current psychosocial input will be positively associated with the participants' perception of their ability to identify and manage prodromal symptoms. (one-tailed) This hypothesis was explored through the Spearman rho correlational test as the data did not meet assumptions for parametric tests.

4.3.2 Exploratory analyses

To investigate the relationship between individual, disorder, and treatment-related variables, univariate and bivariate statistical tests were carried out. These tests were carried out to explore the following research questions:

The data were also used to explore the following research questions:

i) Are the following factors associated with participants' perception of their ability to identify and manage prodromal symptoms: time since diagnosis, gender, age, number of episodes experienced, and current mood state?

ii) Does the consistency of prodromal symptoms (across episodes) have an impact on participants' perception of their ability to identify and manage prodromal symptoms?

iii) Does the ability to identify prodromal symptoms when they first present have an impact on participants' perception of their ability to identify and manage prodromal symptoms?

iv)Is the polarity of the prodromal symptom associated with the participants' perception of their ability to manage manic and depressive prodromal symptoms?

Table 4.2 provides a summary of how the variables of interest were measured.

Table 4.2 Summary of how the individual, disorder, and treatment-related variables were measured

Variables	How information obtained/measured
Individual-related variables	
Age	Demographic Questionnaire.
Gender	Demographic Questionnaire.
General self-efficacy	The aggregate score from the participant's responses to the 10 items on the GSES.
Participant's perception of their ability to identify manic and depressive prodromal symptoms	Participants' responses to questions 6 & 8 in the Demographic Questionnaire in which they are asked to state if they believe they can identify manic/depressive prodromes. Response format: yes, no, or sometimes.
Participants' perception of their ability to manage manic and depressive prodromal symptom	Participants' responses to questions 7 & 9 in the Demographic Questionnaire in which they are asked to state if they believe they can manage manic/depressive prodromes. Response format: yes, no, or sometimes.
Disorder-related variables	
Current mood state	Assessed from self-report information provided in the ISS. Algorithm specified by the authors (Bauer *et al.*, 2001) used to classify current mood state.
Number of manic and depressive episodes experienced	Demographic Questionnaire: a definition of what constitutes an episode (e.g. hospitalisation) was not provided.
Time since diagnosis	Demographic Questionnaire: year in which the questionnaire was completed was subtracted from the year the diagnosis was received.
Consistency of manic and depressive symptoms across episodes	Demographic Questionnaire response to question 10 & 11. Response format: yes or no

Consistency of manic and depressive prodromal symptoms across episodes	Demographic Questionnaire: response to questions 12 & 13. Response format: yes or no
Treatment-related variables	
Role of significant others in management of bipolar disorder	Demographic Questionnaire response to question 5(a) (response format: yes, no) and qualitative response to 5(b). Social network explored through data from the SOS questionnaire.
Level of psychosocial input received (present and current combined)	Response to question 4 in Demographic Questionnaire. Psychosocial input equals the number of services (i.e. day unit, self-help groups, CPN, clinical psychology) individual has had contact (range 0 to 5).

4.3.3 Preliminary analyses: Results

Information regarding all significant statistical relationships is provided below.

4.3.3.1 Variable: Time since diagnosis

As the variable time since diagnosis was not normally distributed ($Z = 1.637$, $p = .009$) non-parametric tests were used to explore if there was a significant relationship between time since diagnosis and the following variables:

- Individual-related: general self-efficacy, age, and gender;
- Disorder-related: number of manic and depressive episodes experienced; and
- Treatment-related: psychosocial input, and role of significant others in helping to manage bipolar disorder.

No significant relationships were found between the variable time since diagnosis and the disorder-related variables. Information relating to the non-significant results is provided in Appendix 21 section 3.

4.3.3.1.1 Time since diagnosis and individual-related variables

A significant positive moderate association was found for time since diagnosis and age, *rho* = .445, $p < .001$.

4.3.3.1.2 Time since diagnosis and treatment-related variables

A moderate positive significant association was found for psychosocial input received and time since diagnosis, *rho* = .208, $p = .037$.

4.3.3.2 Variable: Age

The variable age was statistically examined in relation to:

- Individual-related variables: general self-efficacy;
- Treatment-related variables: psychosocial input, role of significant others; and
- Disorder-related variables: number of episodes experienced.

As the variable age was normally distributed ($Z = 6.88$, $p = .731$) when the variable of interest satisfied parametric assumptions, parametric tests were used. When assumptions for parametric tests were not satisfied, the non-parametric equivalent test was used. No significant relationships were found for age and the individual and the treatment-related variables. Refer to Appendix 21 section 4 for information regarding the non-significant findings.

4.3.3.2.1 Age and disorder-related variables

Age and the number of manic episodes experienced by participants were significantly correlated; a small positive effect was found, *rho* = .250, $p = .037$. However, no

significant relationship was found for age and number of depressive episodes experienced as *rho* = .012, *p* = .923.

4.3.3.3 Variable: Help from significant others in managing bipolar disorder

Help from a significant other (help received/help not received) was considered in relation to the following variables:

- Individual-related: general self-efficacy, age, gender;
- Disorder-related: number of manic and depressive episodes experienced, diagnosis type; and
- Treatment-related: psychosocial input.

No statistically significant relationships were found between help from significant others and the variables of interest. Refer to Appendix 21 section 5.1 to 5.3 for information regarding the non-significant findings.

Participants were asked to briefly describe the help they received from a significant other. This information was used to categorise help received as either: i) emotional and/or practical (e.g. provide caring support and/or help with household chores) or ii) prodromal monitoring-related. A total of 16 (32.65 percent) participants received emotional/practical support and 33 (67.35 percent) received prodromal monitoring-related support. When type of help was entered as an IV, no significant effects were found for the variables time since diagnosis, age, self-efficacy, or level of psychosocial input. Refer to Appendix 21 section 5 for information regarding the non-significant findings concerning type of help and the aforementioned variables.

The type of help received was examined in relation to participants' view of their ability to identify and manage prodromal symptoms. Table 4.3 provides a summary of the participants' perception of their ability to identify and manage prodromes in relation to the type of support they received from a significant other.

Table 4.3 Summary of perception of ability to identify and manage prodromes in relation to type of help received from significant other

	Type of help	
	Emotional/practical *N* (%)	Prodromal monitoring *N* (%)
Able to identify manic prodromes		
No	4 (25)	6 (18.18)
Sometimes	8 (50)	13 (39.40)
Yes	4 (25)	14 (42.42)
Able to identify depressive prodromes		
No	3 (18.75)	7 (21.21)
sometimes	6 (37.50)	5 (15.15)
yes	7 (43.75)	21 (63.64)
Able to manage manic prodromes		
No	3 (18.75)	8 (24.24)
Sometimes	10 (62.50)	18 (54.55)
yes	3 (18.75)	7 (21.21)
Able to manage depressive prodromes		
No	3 (18.75)	9 (27.27)
Sometimes	8 (50)	15 (45.46)
Yes	5 (31.25)	9 (27.27)

A 2 x 3 Pearson chi-square test was used to explore whether perception of ability to identify and manage prodromes was associated with the type of help received. A significant difference was found between participants' perception of ability to manage manic prodromes and the type of support they received, $\chi^2 = 12.53$, d.f. $= 2$, $p = .002$. Based on descriptive statistics in Table 4.3, participants who received emotional/practical support were more likely to be able to identify their symptoms sometimes, whereas participants who received disorder-related support were more able to identify their symptoms all of the time. Participants' ability to identify depressive prodromes was also associated with type of help, $\chi^2 = 12.54$, d.f. $= 2$, $p = .002$. The

descriptive statistics indicated that participants who received disorder-related support were more able to identify depressive prodromes. No significant effect was observed for participants' perception of their ability to manage prodromal symptoms and the type of help provided by significant others. (Refer to Appendix 21 section 5).

4.3.3.4 Variables: Actual and ideal emotional and practical support

Support from significant others was also considered in relation to the data from the SOS questionnaire. The SOS provides information on the actual and ideal level of support received from significant others, therefore, data for the following variables were summarised from the participants' responses to the SOS:

- actual emotional support
- ideal emotional support
- actual practical support
- ideal practical support
- discrepancy between ideal and actual emotional support
- discrepancy between the ideal and actual practical support

Ninety-two participants completed the SOS questionnaire. Some participants stated that they did not wish to complete the questionnaire because they believed they did not have a significant other person in their life to base their answers on. On average participants provided information for 4.42 relationships (SD = 2.23, range = 1-7). Participants discussed their view of support for a range of significant others (e.g. mother, father, spouse, friend, sibling, community psychiatric nurse, and in-laws). Table 4.4 provides a summary of descriptive information based on the data provided for all type of relationships.

Table 4.4 The mean (SD) ratings of support for the participants' relationships with significant others

	All roles *M* (SD)
Actual emotional	2.94 (1.64)
Ideal emotional	3.12 (1.78)
Actual practical	3.20 (1.97)
Ideal practical	2.93 (1.70)
Discrepancy: emotional	.72 (.65)
Discrepancy: practical	.62 (.63)

Paired t-tests were used to examine if there were significant differences for the actual and ideal level of emotional and practical support received from significant others. A significant difference was observed for emotional support $t = 2.65$, d.f. = 91, $p = .01$ and practical support $t = 4.07$, d.f. = 91, $p < .001$. A review of the descriptive information in Table 4.4 indicates that the participants would like to receive more emotional support and less practical support.

When comparisons were made between the type of support received, a significant difference was observed between actual emotional and actual practical support received $t = 3.18$, d.f. = 91, $p = .002$. A significant difference was also found for ideal emotional and practical support $t = 4.03$, d.f. = 91, $p < .001$. A review of the descriptive statistics in Table 4.4 indicates that participants believed they received more practical than emotional support. When ideal support was reviewed the results indicated that participants would like to have more emotional support from significant others.

The relationship between actual and ideal emotional and practical support was reviewed in relation the following variables:

- Individual-related: age, and gender;
- Disorder-related: number of episodes experienced, mood state, and time since diagnosis.

There were no significant relationships between actual and ideal emotional and practical support and the individual-related and disorder variables. Refer to Appendix 21 section 6 for additional information.

Table 4.5 provides descriptive information for the following relationships: mother, father, and spouse.

Table 4. 5 Mean (SD) scores for actual and ideal support received (mother, father, spouse relationships)

support	Mother ($N = 25$) *M* (SD)	Father ($N = 9$) *M* (SD)	Spouse ($N = 33$) *M* (SD)
Actual support	5.20 (.86)	5.19 (1.71)	5.88 (1.12)
Ideal support	5.37 (1.69)	5.66 (1.11)	6.00 (1.42)
Discrepancy	.83 (.85)	1.11 (1.55)	.49 (.74)

The descriptive statistics indicated that the least discrepancy between actual and ideal support was for the relationships with spouses.

4.3.3.5 Variable: General self-efficacy

Participants' general self-efficacy scores were explored in relation to the following variables:

- Individual-related: gender;
- Disorder-related: number of episodes experienced, diagnosis, and current mood state; and
- Treatment-related: role of significant others and psychosocial input.

As the variable self-efficacy was normally distributed ($Z = .836$, $p = .486$) when homogeneity of variance was met parametric tests were used. When this assumption was not met, non-parametric tests were used. No significant relationships were found for

self-efficacy and individual and disorder-related variables. Refer to Appendix 21 section 7 for information regarding the non-significant findings.

4.3.3.5.1 General self-efficacy and treatment-related variables

Self-efficacy scores and level of psychosocial input received were negatively correlated, $r = -.195$, $p = .05$. This small correlation indicates that higher levels of psychosocial input are associated with lower general self-efficacy scores.

4.3.3.6 Variable: Identification of manic and depressive prodromes

Table 4.6 provides a summary of participants' perception of their ability to identify manic and depressive prodromal symptoms when they first present.

Table 4.6 Participants' perception of their ability to identify prodromes

	Unable to identify *N* (%)	Sometimes identify *N* (%)	Able to identify *N* (%)
Manic prodromes	14 (13.9)	46 (45.5)	41 (40.6)
Depressive prodromes	18 (17.8)	25 (24.8)	58 (57.4)

The Pearson chi-square test was used to investigate if there was an effect of polarity with reference to participants' ability to identify prodromes. No significant difference was found when participants' ability to identify or not identify prodromal symptoms was examined. Refer to Appendix 21 section 8 for additional information.

Participants' perception of their ability to identify manic and depressive prodromal symptoms was statistically explored in relation to:

- Individual-related variables: general self-efficacy, age, and, gender;
- Disorder-related variables: number of episodes experienced, time since diagnosis, current mood state, and consistency of prodromal symptoms; and
- Treatment-related variables: role of significant others, and psychosocial input.

4.3.3.6.1 Manic prodromal symptoms

No significant statistical relationships were found for treatment-related variables in relation to participants' ability to identify manic prodromal symptoms. For information on the non-significant findings refer to Appendix 21 section 8.1.3.

4.3.3.6.2 Identification of manic prodromes and individual-related variables

Five males (11.91 percent) stated they could not identify symptoms, 15 (35.71 percent) believed they could sometimes identify symptoms, and 22 (52.38 percent) believed they could identify manic prodromal symptoms. Nine females (15.26 percent) believed they were unable to identify symptoms, 19 (32.20 percent) stated they could sometimes identify symptoms, and 31 (52.54 percent) stated they could identify symptoms. A 2 x 3 Pearson chi-square test for categorical data were used to explore whether there was an association between gender and ability to identify manic prodromal symptoms. A significant difference was found, $\chi^2 = 3.72$, d.f. $= 2$, $p = .054$. This result is further explored in the primary analyses. No significant associations were found for the participants' perception of their ability to identify manic prodromal symptoms and general self-efficacy scores and age. Refer to Appendix 21 section 8.1.1.

4.3.3.6.3 Identification of manic prodromes and disorder-related variables

Table 4.7 provides a summary of the number of participants who experienced consistent and inconsistent manic prodromal symptoms with reference to the participants' perception of their ability to identify manic prodromal symptoms.

Table 4.7 Summary of participants' experience of manic prodromes in relation to perceived ability to identify prodromes

	Unable to identify *N* (%)	Can sometimes identify *N* (%)	Able to identify *N* (%)
Inconsistent prodromal symptoms	9 (17.65)	29 (56.86)	13 (25.49)
Consistent prodromal symptoms	5 (10.00)	17 (34.00)	28 (56.00)

As the data were categorical, a 2 x 3 Pearson chi-square test was used to examine the relationship between the participants' perceptions of their ability to identify manic prodromes and consistency of manic prodromes across episodes (consistent or inconsistent). A significant relationship was found, $\chi^2 = 9.752$, d.f. = 2, $p = .008$. No significant associations were found between participants' perception of their ability to identify manic prodromal symptoms and the variables time since diagnosis and mood state (refer to Appendix 21 section 8.1.2 for more information).

4.3.3.6.4 Identification of depressive prodromes

No significant relationships between ability to identify depressive prodromes and individual and treatment-related variables were found. For information on the non-significant findings refer to Appendix 21 section 8.2.1 and 8.2.3.

4.3.3.6.5 Identification of depressive prodromes and disorder-related variables

Table 4.8 provides a summary of participants' perception of their ability to identify depressive prodromal symptoms in relation to whether prodromal symptoms are consistent across episodes.

Table 4.8 Summary of participants' experience of depressive prodromal symptoms in relation to perceived ability to identify symptoms

	Unable to identify *N* (%)	Can sometimes identify *N* (%)	Able to identify *N* (%)
Inconsistent prodromes	11 (28.21%)	12 (30.77%)	16 (41.02%)
Consistent prodromes	7 (11.29%)	13 (20.97%)	42 (67.74%)

A 2 x 3 Pearson chi square test was carried out to explore if there was a significant relationship between identification of depressive prodromes and consistency of depressive prodromes across episodes; a significant relationship was found, χ^2 =7.748, d.f. = 2, p = .021. No other significant relationships were found with the disorder-related variables.

4.3.3.7 Variable: Management of prodromes

Table 4.9 provides a summary of participants' views of their ability to manage manic and depressive prodromal symptoms.

Table 4.9 Participants' perception of their ability to manage manic and depressive prodromes

	Unable to mange *N* (%)	Sometimes manage *N* (%)	Able to manage *N* (%)
Manic prodromes	18 (17.82)	57 (56.43)	26 (25.75)
Depressive prodromes	24 (23.76)	50 (49.51)	27 (26.73)

When statistical comparisons were made between participants' ability to manage manic and depressive prodromes no significant differences were found for participants' ability to manage prodromal symptoms. Refer to Appendix 21 section 9 for additional information.

The sample's ability to manage manic and depressive prodromes was explored in relation to:

- Individual-related variables: general self-efficacy, age, and gender;
- Disorder-related variables: time since diagnosis, number of episodes experienced, current mood state, participants' perception of their ability to identify prodromes, consistency of prodromes; and
- Treatment-related variables: role of significant others and psychosocial input.

4.3.3.7.1 Management and manic prodromes

No significant relationships were found between treatment-related variables and participants' perceptions of their ability to manage prodromal symptoms. For information on the non-significant findings refer to Appendix 21 section 9.1.2.

4.3.3.7.1.1 Management of manic prodromes and individual-related variables

Participants who were able to manage prodromal symptoms had a mean general self-efficacy score of 29.77 (SD = 5.37, range = 18-38). Participants who reported that they could sometimes manage these prodromes a mean score of 25.60 (SD = 6.11, range = 10-39). Participants who said they could not manage manic prodromes had a mean self-efficacy score of 24.28 (SD = 6.43, range = 15-39). As assumptions of normal distribution ($Z = .836$, $p = .486$) and homogeneity of variance were met (Levene's test = 0.101, d.f. = 2, 98, $p = .904$) a one-way ANOVA was carried out to investigate if there were between group differences regarding self-efficacy scores. A significant effect was found as $F = 12.75$, d.f. = 2, 98, $p = .004$.

The Tukey post hoc test was used to explore the significant difference. A significant difference was found between self-efficacy scores for participants who stated they could manage manic prodromes and those who stated they were unable to manage symptoms. A significant difference was also found for participants who could manage and those who perceived that they could sometimes manage symptoms. There was no significant

difference between the 'sometimes could' and the 'could not' manage groups. A non-significant association was found between participants' perception of their ability to manage manic prodromal symptoms and the variables age and gender (refer to Appendix 21 section 9.1.1 for additional information).

4.3.3.7.1.2 Management of manic prodromes and disorder-related variables

Participants who stated they could manage manic prodromal symptoms had experienced a median number of four manic episodes (range = 1-100). Those who stated they could sometimes manage symptoms reported experiencing a median of five episodes (range = 1-216). A median number of seven episodes (range = 1-300) were experienced by participants who stated they could not manage prodromal symptoms.

As the number of manic episodes experienced was not normally distributed the Kruskal-Wallis test was used to determine if there were between-group differences. A significant difference was observed as $\chi^2 = 6.85$, d.f. = 2, $p = .033$. The Mann-Whitney U test was used to explore the significant effect. A significant difference was found for participants who could not and could sometimes manage manic symptoms as $U = 235.5$, $p = .032$. A significant difference was also found between participants who could sometimes manage symptoms and those who stated they can manage symptoms as $U = 298.5$, $p = .028$.

No significant difference was observed between participants who stated they cannot manage symptoms and those who said they can manage symptoms as $U = 174.5$, $p = .908$.

Table 4.10 provides a summary of the participants' ability to manage manic prodromal symptoms in relation to their perception of their ability to identify prodromal symptoms.

Table 4.10 Summary of participants' perception of their ability to manage manic prodromes in relation to ability to identify manic prodromes

	Unable to manage *N* (%)	Sometimes manage *N* (%)	Able to manage *N* (%)
Unable to identify	11 (61.1)	2 (11.11)	5 (27.78)
Sometimes able to identify	3 (5.26)	42 (73.69)	12 (21.05)
Able to identify	0 (0%)	2 (7.69%)	24 (92.31%)

When the relationship between participants' ability to manage prodromal symptoms and their perceptions of their ability to identify symptoms was explored via a 3 x 3 Pearson chi-square test a significant relationship was found, $\chi^2 = 17.60$, d.f. = 2, $p < .001$. Based on the descriptive data it would appear that participants who are able to identify manic prodromes are more likely to be able to manage these symptoms. This finding will be explored in more detail in the primary analysis. No significant associations were found for time since diagnosis and current mood state with reference to the participants' perception of their ability to manage prodromal symptoms (refer to Appendix 21 section 9.1.3 for additional information).

4.3.3.7.2 Management of depressive prodromes

No significant relationships were found for the individual and treatment-related variables and perception of the participants' ability to manage depressive prodromal symptoms. For information on the non-significant findings refer to Appendix 21 section 9.2.1 and 9.2.3.

4.3.3.7.2.1 Management of depressive prodromes and disorder-related variables

Table 4.11 provides a summary of participants' view of their ability to manage depressive prodromal symptoms in relation to their perception of the consistency of their depressive prodromal symptoms.

Table 4.11 Summary of participants' experience of depressive prodromes in relation to perceived ability to manage symptoms

	Unable to manage *N* (%)	Can sometimes manage *N* (%)	Able to manage *N* (%)
Inconsistent prodromes	11 (28.21)	21 (53.84)	7 (17.95)
Consistent prodromes	13 (20.97)	29 (46.77)	20 (32.26)

A 2 x 3 Pearson chi-square test was used to explore whether a relationship exists between consistency of prodromal symptoms across episodes and participants' view of their ability to manage prodromal symptoms. A significant association was found as $\chi^2 = 5.328$, d.f. = 1, $p = .022$. Based on the descriptive data it appears that participants who experienced consistent depressive prodromes were more likely to be able to mange these prodromes. This significant association will be explored in more detail in the primary analysis.

Table 4.12 provides a summary of participants' ability to manage prodromal symptoms in relation to their perception of their ability to identify manic prodromal symptoms.

Table 4.12 Summary of participants' perception of their ability to manage depressive prodromes in relation to ability to identify depressive prodromes

	Unable to manage *N* (%)	Sometimes manage *N* (%)	Able to manage *N* (%)
Unable to identify	13 (72.22)	3 (16.67)	2 (11.11)
Sometimes able to identify	2 (8.00)	21 (84.00)	2 (8.00)
Able to identify	9 (15.52)	26 (44.83)	24 (39.65)

When the relationship between participants' ability to manage prodromal symptoms and their perception of their ability to identify symptoms was explored via a 3 x 3 Pearson chi square test a significant relationship was found as $\chi^2 = 27.109$, d.f. = 2, $p < .001$. The descriptive data indicates that participants who believe they are unable to identify prodromes also believe that they are unable to manage these symptoms. This relationship will be explored in more detail in the primary analysis. A non-significant relationship was found for the variables time since diagnosis, number of episodes experienced, and current mood state (refer to Appendix 21 section 9.2.2 for additional information).

4.4 Strategy of analysis: Participants' experience of prodromes

A sub-sample of 48 participants completed the Prodromal Experience Questionnaire. The questionnaire contained a list of 36 common manic and depressive prodromal symptoms. The prodromal symptoms can be categorised by polarity and type (i.e. affective, cognitive, and behavioural).

To investigate if there is a significant difference in the number of manic and depressive prodromes that participants endorsed as experienced, identified when the symptom first presents, consistently experienced, and manageable statistical tests were carried out.

Statistical tests were also conducted to explore if prodromal type has an impact upon participants' perception of their ability to identify and manage prodromes.

In addition, participants' perception of their ability to identify and manage cognitive, affective, and behavioural manic and depressive prodromes was statistically analysed in relation to:

- Individual-related variables: age, gender, general self-efficacy;
- Treatment-related: psychosocial input, role of significant others; and
- Disorder-related: time since diagnosis, number of manic and depressive episodes experienced, mood state, and consistency of symptoms experienced.

As the data did not violate the assumption of normal distribution parametric tests were used to explore the association between variables of interest. The statistical analyses associated with participants' experience of prodromal symptoms will be used to explore the research question:

Are types of prodromal symptoms (i.e. cognitive, affective, and behavioural) associated with the participants' perception of their ability to identify and manage manic and depressive prodromal symptoms?

Prior to the data being reviewed information relating to demographic and clinical features of the sub-sample of participants who completed the Prodromal Experience Questionnaire will be presented in section 4.4.1.

4.4.1 Results: Experience of prodromal symptoms

Twenty-nine females (60.42 percent) and 19 males (39.58 percent) completed the Prodromal Experience Questionnaire. Table 4.13 provides a summary of the clinical and demographic factors associated with the sub-sample of participants.

Table 4.13. Descriptive information (clinical and demographic variables) for the sub-sample who completed the Prodromal Experience Questionnaire

	Sub-sample of participants (N = 48)	
	M *(SD)*	Range
Age	47.17 (9.64)	24 - 72 yrs
No. of manic episodes	20.21 (57.06)	1 - 216
No. of depressive episodes	25.24 (27.57)	1 - 144
Time since diagnosis	12.90 (8.20)	1 - 40 yrs

A comparison of the descriptive information for the total sample in table 4.2 shows that the sub-sample did not significantly differ with regard to the above clinical and demographic variables. No significant differences were found when the sub-sample was compared to the remaining participants from the total sample with reference to the above variables. Refer to Appendix 21 section 10 for additional information.

Table 4.14 provides a summary of the prodromal symptoms that were most commonly endorsed by participants with reference to experience of manic and depressive prodromes, ability to identify prodromes when they first present, and prodromes that are consistently experienced.

Table 4.14 The most commonly endorsed prodromes by polarity

	Most often endorsed item	(% of sub-sample who endorsed item)
Manic		
Experienced	Increased activity	(89.58)
	Decreased sleep	(89.58)
	Elevated mood	(89.58)
Identified when first present	Increased activity	(52.08)
	Elevated mood	(50.00)
	Decreased sleep	(50.00)
Consistently experienced	Increased activity	(64.58)
	Elevated mood	(60.42)
	Racing thoughts	(60.42)
Managed	Increased activity	(39.58)
	Elevated mood	(35.40)
	Decreased sleep	(31.25)
Depressive		
Experienced	Low self confidence	(87.50)
	Can't face tasks	(87.50)
	Low self-esteem	(87.50)
Identified when first present	Low self-esteem	(50.00)
	Loss of energy	(50.00)
	Not feeling like seeing people	(47.92)
Consistently experienced	Loss of energy	(56.25)
	Concentration difficult	(52.08)
	Negative thinking	(50.00)
	Low motivation	(50.00)
	Not interested in activities	(50.00)
	Feeling sad	(50.00)
Managed	Can't face normal tasks	(22.92)
	Nothing enjoyable	(22.92)
	Feeling sad	(22.92)
	Negative thinking	(22.92)

A review of the information in the above table indicates that a high percentage of the sub-sample had experienced similar prodromal symptoms. There is a considerable reduction in the percentage of participants who believe that they are able to manage prodromal symptoms. Furthermore, with the exception of consistently experienced prodromes, the three most common manic prodromal symptoms were mentioned in relation to prodromes that are experienced, identifiable when they first present, and manageable. When commonly endorsed depressive prodromes are reviewed it is apparent that different prodromes are identified as being experienced, consistently experienced, identifiable when they first present, and manageable.

Table 4.15 provides descriptive information on the number of prodromal symptoms that participants stated they experienced, were able to identify when they first presented, were consistently experienced, and were able to manage.

Table 4.15 Summary of participants' experience of prodromes

	Males (N =19) *M* (SD)	Females (N= 29) *M* (SD)	Total Sample (N = 48) *M (*SD)
Manic prodromes			
Experienced	13.47 (5.38)	14.90 (3.62)	14.33 (4.40)
Consistently experienced	6.84 (6.31)	8.07 (5.65)	7.58 (5.86)
Identified when first present	5.79 (6.28)	6.03 (5.53)	5.94 (5.77)
Managed	3.21 (4.99)	4.62 (5.34)	4.06 (5.20)
Depressive prodromes			
Experienced	12.26 (6.76)	15.86 (2.95)	14.44 (4.88)
Consistently experienced	5.74 (6.24)	9.31 (6.35)	7.90 (6.49)
Identified when first present	5.63 (7.18)	8.55 (6.89)	7.40 (7.08)
Managed	2.00 (4.19)	4.24 (5.60)	3.35 (5.15)

The range was 0-18, with the exception of males' experience of manic prodromes (range = 2-18).

Independent t-tests were used to test for effect of gender regarding experience of prodromes. No significant differences were observed. For information on the non-significant findings refer to Appendix 21 section 10.

To investigate the experience of the total sample, paired t-tests were used. No significant differences with observed for the experience of prodromes by polarity.

4.4.2. Participants' experience of affective prodromes

Table 4.16 provides a summary of descriptive statistics associated with participants' experiences of affective prodromes.

Table 4.16 Summary of participants' experience of affective prodromes

	Males (N = 19) *M* (SD)	Females (N = 29) *M* (SD)	Total Sample (N = 48) *M* (SD)
Manic prodromes			
Experienced	3.74 (1.73)	4.34 (.94)	4.10 (1.33)
Consistently experienced	1.68 (1.92)	2.24 (1.69)	2.02 (1.78)
Identified when first present	1.32 (1.73)	1.79 (1.42)	1.60 (1.55)
Managed	0.79 (1.44)	1.28 (1.56)	1.08 (1.51)
Depressive prodromes			
Experienced	2.68 (1.64)	3.55 (.827)	3.21 (1.27)
Consistently experienced	1.32 (1.49)	2.00 (1.56)	1.73 (1.55)
Identified when first present	1.21 (1.75)	1.93 (1.65)	1.65 (1.71)
Managed	0.58 (1.17)	1.03 (1.40)	0.85 (1.32)

The range for the manic prodromes was 0-5 and 0-4 for depressive prodromes.

Independent t-tests were used to investigate if gender had an impact on how prodromes are experienced. A significant effect of gender was observed for the number of depressive prodromes that participants stated they experienced $t = 2.43$, d.f. = 46, $p = 0.01$. Female participants reported that they experienced more affective depressive prodromes (Mean = 3.55, SD = .827) compared with the male participants (Mean = 2.68, SD = 1.64).

Paired t-tests were used to investigate if there was a significant difference in the samples' experience of manic and depressive affective prodromes. There was a significant difference between the numbers of affective prodromes experienced, $t = 6.86$, d.f. = 47, $p < .001$. The descriptive statistics indicate that more manic affective prodromes were experienced (Mean = 4.10, SD = 3.21) than depressive affective prodromes (Mean = 3.21, SD = 1.27).

4.4.3 Participants' experience of cognitive prodromes

Table 4.17 provides a summary of descriptive information associated with male, female, and the total research sample's experience of cognitive prodromes.

Table 4.17 Summary of participants' experience of cognitive prodromes

	Males *M* (SD)	Females *M* (SD)	Total Sample *M* (SD)
Manic prodromes			
Experienced	4.58 (2.06)	4.86 (1.36)	4.75 (1.66)
Consistently experienced	2.16 (1.19)	2.62 (2.19)	2.44 (2.18)
Identified when first present	1.95 (2.17)	1.76 (2.05)	1.83 (2.08)
Managed	0.89 (1.79)	1.34 (1.97)	1.17 (1.89)
Depressive prodromes			
Experienced	4.32 (2.48)	5.59 (.682)	5.08 (1.71)
Consistently experienced	2.32 (2.50)	3.17 (2.35)	2.83 (2.42)
Identified when first present	2.05 (2.55)	2.76 (2.41)	2.48 (2.46)
Managed	0.58 (1.42)	1.52 (2.08)	1.15 (1.89)

The range for the manic prodromes was 0-5 and 0-4 for depressive prodromes.

Independent t-tests were used to assess if the experience of males and females significantly differed. A significant difference between the number of cognitive depressive prodromes experienced by male and female participants was observed $t = 2.65$, d.f. = 46, $p = .01$. The female participants experienced more depressive prodromes in comparison to the male participants (Male participants: Mean = 4.32, SD = 2.48; Female participants: Mean = 5.59, SD = .682).

Paired t-tests were used to examine participants' experiences with reference to the polarity of the prodrome. A significant difference was found between the number of

cognitive prodromes that are identified when they first present $t = 2.24$, d.f. = 47, $p = .030$. The participants' responses indicated that more depressive prodromal symptoms were identified (Mean = 2.48, SD = 2.46).

4.4.4 Participants' experience of behavioural prodromes

Table 4.18 provides a summary of the participants' experience of behavioural prodromes. As above, the information is presented for males and female participants and also for the sample as a whole.

Table 4.18 Summary of participants' experience of behavioural prodromal symptoms

	Males *M* (SD)	Females *M* (SD)	Total Sample *M* (SD)
Manic prodromes			
Experienced	5.21 (2.02)	5.66 (1.59)	5.48 (1.76)
Consistently experienced	3.00 (2.56)	3.21 (2.13)	3.13 (2.28)
Identified when first present	2.53 (2.59)	2.48 (2.46)	2.50 (2.48)
Managed	1.53 (2.14)	1.97 (2.28)	1.79 (2.21)
Depressive prodromes			
Experienced	5.26 (2.77)	6.69 (1.23)	6.13 (2.08)
Consistently experienced	2.11 (2.40)	4.14 (2.80)	3.33 (2.81)
Identified when first present	2.26 (2.56)	3.93 (2.83)	3.27 (2.82)
Managed	0.84 (1.74)	1.66 (2.54)	1.33 (2.27)

The range for the manic prodromes was 0-5 and 0-4 for depressive prodromes.

Independent t-tests were used to analyse the data concerning experience of cognitive prodromes. Significant differences were observed for the number of depressive behavioural prodromes experienced by male and female participants ($t = 2.44$, d.f. = 46, $p = .018$), the number always experienced ($t = 2.59$, d.f. = 46, $p = .013$) and the number that can be identified when they first present ($t = 2.07$, d.f. = 46, $p = .044$) The descriptive statistics (refer to Table 4.18) show that female participants experienced more depressive behavioural prodromal symptoms that were more consistent and more readily identifiable in comparison to the male participants.

To examine the effect of polarity for the sample's experience of behavioural prodromes paired t-tests were used. Significant differences were observed between the numbers of behavioural prodromal symptoms experienced ($t = 2.36$, d.f. = 47, $p = .022$), identified ($t = 2.11$, d.f. = 47, $p = .04$), and managed ($t = 2.04$, d.f. = 47, $p = .047$). The descriptive statistics show that more depressive behavioural prodromes were experienced compared to manic prodromes (Mean = 6.13, S. D. = 2.08; Mean = 5.48, S.D. = 1.76). Likewise, depressive prodromal symptoms were viewed as being more identifiable than manic prodromal symptoms (Mean = 3.27, S.D. =2.82; Mean = 2.50, S.D. = 2.48). More manic prodromal symptoms, however, were viewed as manageable (1.79, S.D. = 2.21) compared to depressive prodromal symptoms (1.33, S.D. = 2.27).

4.4.5 The relationship between the experience of prodromes and individual, disorder, and treatment-related variables

Significant results from the bivariate statistical analyses for the three types of prodromal symptoms and the individual, disorder, and treatment-related variables of interest are summarised in Table 19. Refer to Appendix 21 section 10.4 for the non-significant results.

Table 4.19. Summary of significant results for prodrome type and individual, disorder, and treatment-related variables

Prodrome type	Variables	Result
Affective		
Manic:	Identify & age	*rho* = -.323, *p* = .029
	Manage & self-efficacy	*rho* = .413, *p* = .004
	Manage & identify	*rho* = .605, *p* = .001
Depressive:	Identify & age	*rho* =-.290, *p* = .050
	Identify & prodrome consistency	*rho* = .344, *p* = .017
	Manage & identify	*rho* = .399, *p* = .005
	Manage & prodrome consistency	*rho* = .280, *p* = .054
Cognitive		
Manic:	Identify & self-efficacy	*rho* = .375, *p* = .009
	Manage & identify	*rho* = .475, *p* = .001
Depressive:	Identify & self-efficacy	*rho* = .321, *p* = .026
	Manage & identified	*rho* = .414, *p* = .003
	Manage & self-efficacy	*rho* = .321, *p* = .026
Behavioural		
Manic:	Identify & self-efficacy	*rho* = .301, *p* = .038
	Manage & identified	*rho* = .475, *p* = .001
Depressive:	Identify & self-efficacy	*rho* = .301, *p* = .038
	Manage & identify	*rho* = .529, *p* = .001

4.4.5.1 Participants' experience of affective prodromes in relation to individual, disorder and treatment-related variables

A moderate negative significant correlation was found for ability to identify manic prodromes when they first present and age. A moderate positive significant correlation was also observed for ability to manage and self-efficacy and ability to manage and number of manic prodromes identified when they first present.

For depressive prodromes, a negative significant association was found for ability to identify symptoms and age (small correlation). This indicates that ability to identify depressive affective prodromes may reduce with age. A moderate positive correlation was found for consistently experienced symptoms and the participants' view of their ability to identify prodromes. When ability to manage depressive affective prodromes was explored a positive moderate correlation was found for number of prodromes identified and a small positive correlation was found for the consistency of prodromes experienced.

4.4.5.2 Participants' experience of cognitive prodromes in relation to individual, disorder, and treatment-related variables

A significant positive association was found between participants' ability to identify manic cognitive prodromes and self-efficacy (moderate correlation). A moderate significant correlation was found for ability to manage these prodromes and number of prodromes that can be identified when they first present.

With regard to depressive cognitive prodromes a significant positive moderate association was found for ability to identify these prodromes and general self-efficacy. A moderate positive significant correlation was also found for ability to manage these prodromes and general self-efficacy. The number of prodromes identified when they first present was also positively significantly correlated with participants' view of their ability to manage depressive cognitive prodromes: the effect size was moderate.

4.4.5.3 Participants' experience of behavioural prodromes in relation to individual, disorder, and treatment-related variables

Participants' ability to identify manic behavioural prodromes, when they first present was positively significantly associated with general self-efficacy (moderate effect size). Significant associations were observed for ability to manage manic behavioural prodromes and number of prodromes identified when they first present (moderate effect size). General self-efficacy was positively significantly associated with participants' ability to identify behavioural depressive prodromes (moderate effect size).

There was a significant positive (large) association between management and number of prodromes identified when they first present. A moderate positive significant association was found for ability to manage behavioural prodromes and consistency of prodromes across episodes.

4.5 Primary Analysis: Strategy of analysis

To identify the impact of the variables that significantly influence participants' ability to identify and manage prodromes four ordinal logistic regression analyses were conducted. This statistical test was chosen as the dependent variable (participants' perception of their ability to identify and manage manic and depressive prodromes) was an ordered polytomous variable (e.g. response options: no, sometimes, yes). Ordinal logistic regression is a common method for modelling relationships between an ordinal DV and multiple IVs (Cohen *et al.*, 2003). This analysis enables cumulative probabilities, odds, and odd ratios for values of the DV, lower than or equal to particular value, to be compared to those for higher values of the DV (Orme & Combs-Orme, 2009).

Separate ordinal logistic regression models were run for each of the four dependent variables (DVs). Predictor variables (PVs) were included if they were significantly associated with the DV as demonstrated in the preliminary analyses. With reference to participants' ability to identify manic and depressive prodromes the same predictor

variables were examined in order to enable comparisons to be made between manic and depressive prodromes.

The individual PVs were entered into the regression separately. For significant associations the cumulative odds, cumulative probabilities, and probabilities for the individual values of the DVs are presented. When more than one PV was significantly related to the DV the analysis was re-run with the inclusion of all relevant predictor variables. Figure 4.1 provides a summary of the PVs that were entered into the logistic ordinal regression analyses.

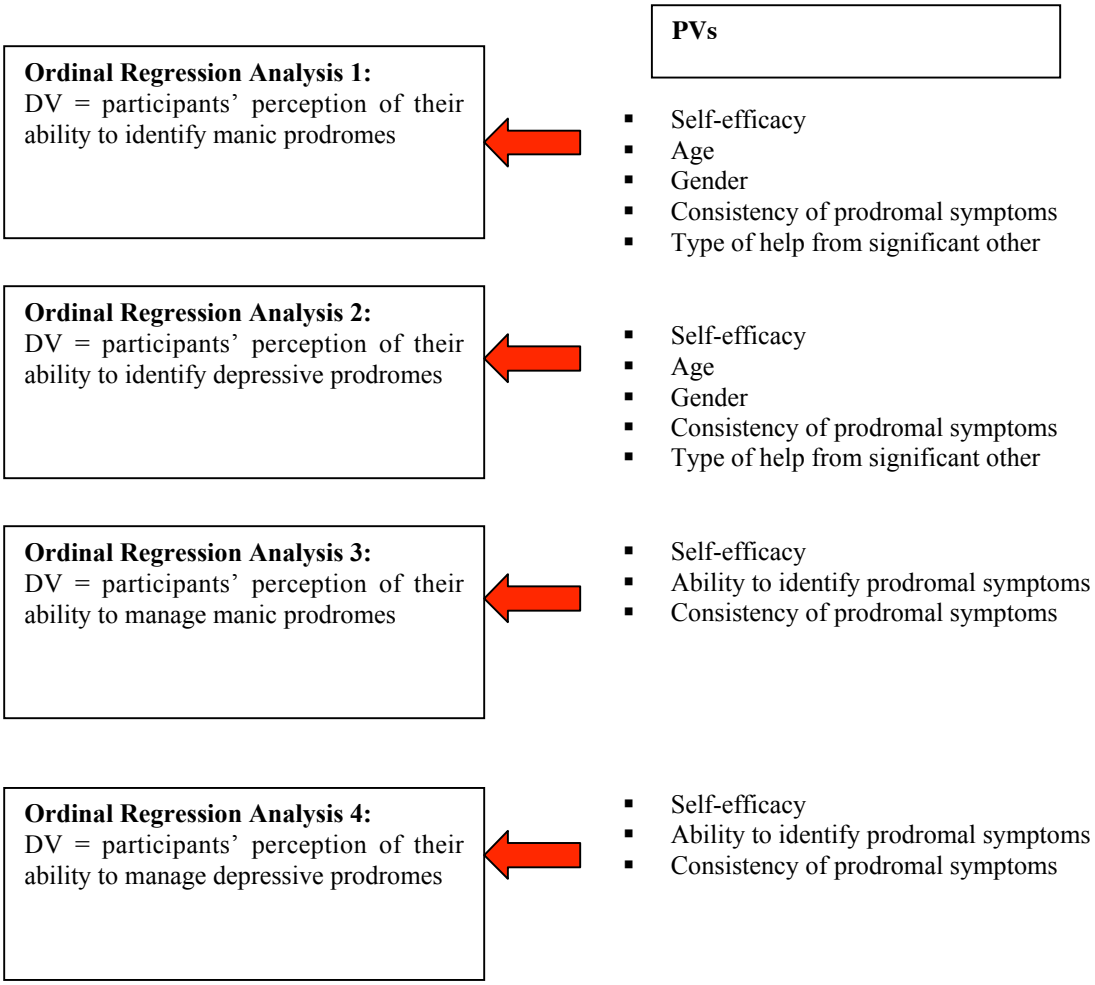

Figure 4.1 Summary of DVs and PVs used in the ordinal logistic regression analyses

Four statistical assumptions are associated with ordinal logistic regression analyses (Orme &Combs-Orme, 2009). The assumptions and information detailing how they were assessed and whether they were violated are discussed below.

Assumption 1: Relevant variables are included in the analysis.
How assessed: The PVs were included based on evidence from the primary analyses.

Assumption 2: Errors for each case are independent from errors of all others.
How assessed: This assumption was met as the participants from whom the DV is measured were sampled independently.

Assumption 3: The absence of perfect multicollinearity.
How assessed: The Variation Inflation Factor (VIF) was used to assess if the tolerance in the amount of variance in the IV was accounted for by the remaining IVs. Tolerance levels of .10 or less were considered problematic and indicated that the IV should not be included in the regression (Cohen, *et al.*, 2003). This assumption was not violated.

Assumption 4: The parallel lines assumption states that the effect of the IVs is the same for all values of the DV.
How assessed: The Parallel Lines Assumption test in PASW 17.0 was used to assess whether this assumption was violated. When this test was applied to the four analyses the results showed that the null hypothesis could not be rejected in analyses 1, however the null hypothesis was rejected in tests 3 and 4. A review of the predictor variables showed that participant's ability to identify manic and depressive prodromes had a direct impact upon this assumption. This variable was, therefore, not included in this analysis. The multinominal logistic regression model can be used when this assumption is violated; however, this analysis does not take account of the ordered DV (DeMaris, 2004). Therefore, information from the univariate and bivariate analyses will be used to explore the impact of participants' perception of their ability to identify prodromal symptoms on prodromal management.

4.5.1 Primary analyses and the research hypotheses and research questions

The results from the primary analysis were used to further explore whether the following research hypotheses were accepted or rejected:

Hypothesis 1: General self-efficacy will be positively associated with participants' perception of their ability to identify and manage manic and depressive prodromal symptoms. (one-tailed)

Hypothesis 2: Social support, in relation to help from significant others in managing bipolar disorder, will be positively associated with the participants' view of their ability to identify and manage prodromal symptoms. (one-tailed)

The following *a priori* research question was also explored:
i) Does the consistency of prodromal symptoms (across episodes) have an impact on participants' perception of their ability to identify and manage prodromal symptoms?

Based on the findings from the preliminary analyses a further research question was explored:

ii) Are the factors gender and age associated with the participants' perception of their ability to identify and manage manic and depressive prodromal symptoms?

4.5.1.1 Primary analysis: The results

4.5.1.1.2 Ordinal logistic regression 1: Ability to identify manic prodromes

Table 4.20 provides a summary of the results from ordinal logistic regression analysis 1 which was used to assess the contribution of age, gender, consistency of symptoms, and self-efficacy in relation to participants' ability to identify manic prodromes.

Table 4.20 Summary of results from ordinal logistic regression 1

						95% confidence interval	
PV	Estimate	Std. Error	Wald (d.f.)	Sig	Exp (B)	Lower bound	Upper bound
Age	-.04	.02	3.67 (1)	.06	.96	-.079	.00
Gender	.67	.39	2.95 (1)	.09	.51	-.095	1.43
Consistency	1.15	.40	8.47 (1)	.00	3.17	1.46	6.90
Self-efficacy	.06	.08	4.24 (1)	.04	1.07	.00	.13
Type of help	.28	.59	.420 (1)	.52	1.32	.57	3.06

Each PV was entered individually into the model

When the PV gender was entered into the regression a positive slope (.67) was found but this did not reach significance level as $p = .09$. When the PV age was entered the result showed that the slope was negative (-.04) thus indicating that with increasing age participants were less able to identify manic prodromes; however, this relationship was not significant. When the PV type of help was entered into the model a non-significant association was found.

The ability to identify manic prodromes was positively associated with the PV self-efficacy. The sign of the slope is positive, therefore indicating that higher self-efficacy scores are associated with ability to identify manic prodromes. The OR = 1.07, therefore, for a standard deviation decrease in self-efficacy, the odds of not being able to identify manic prodromes increases by a factor of 1.07.

When the PV consistency was entered into the ordinal regression a significant positive slope was found, this indicated that participants who experienced consistent symptoms were more able to identify manic prodromes. Figure 4.2 provides a summary of the estimated logits for ‘unable to identify’ prodromes compared with ‘sometimes able’ and ‘able to identify’ prodromes. From the figure it is evident that participants with consistent manic prodromes are more likely to be able to identify manic prodromes when they present.

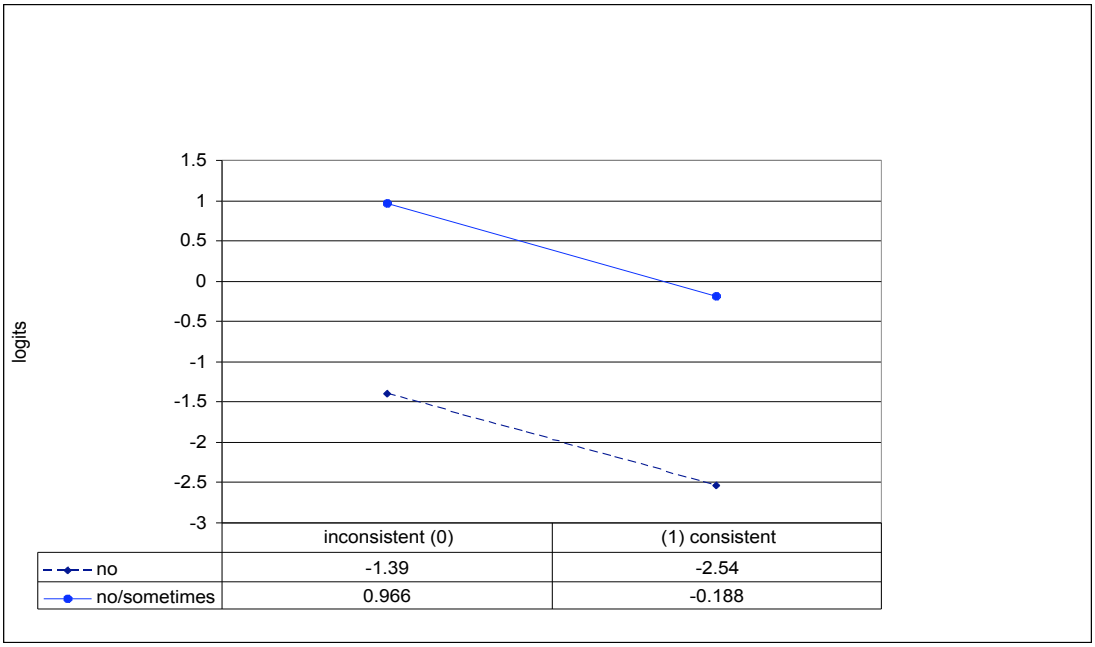

Figure 4.2 Effect of prodromal consistency on participants' perception of their ability to identify manic prodromes

Figure 4.3 provides a summary of the estimated odds. The figure demonstrates that the odds of being unable to identify manic prodromes are lower for participants with inconsistent symptoms.

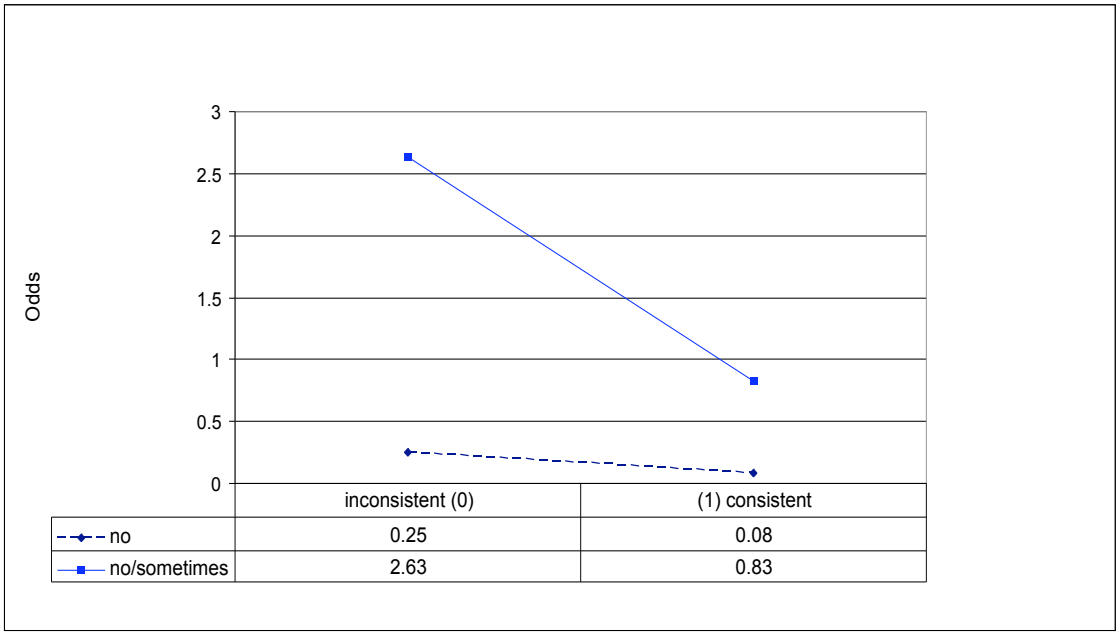

Figure 4.3 Effect of consistency on manic prodrome identification

The cumulative odds for not being able to identify manic prodromes were 92 percent lower for participants who stated they experience consistent manic prodromes.

Figure 4.4 provides a summary of the cumulative probabilities; as above, the figure demonstrates that the probability of not being able identify symptoms is lower for participants with consistent symptoms.

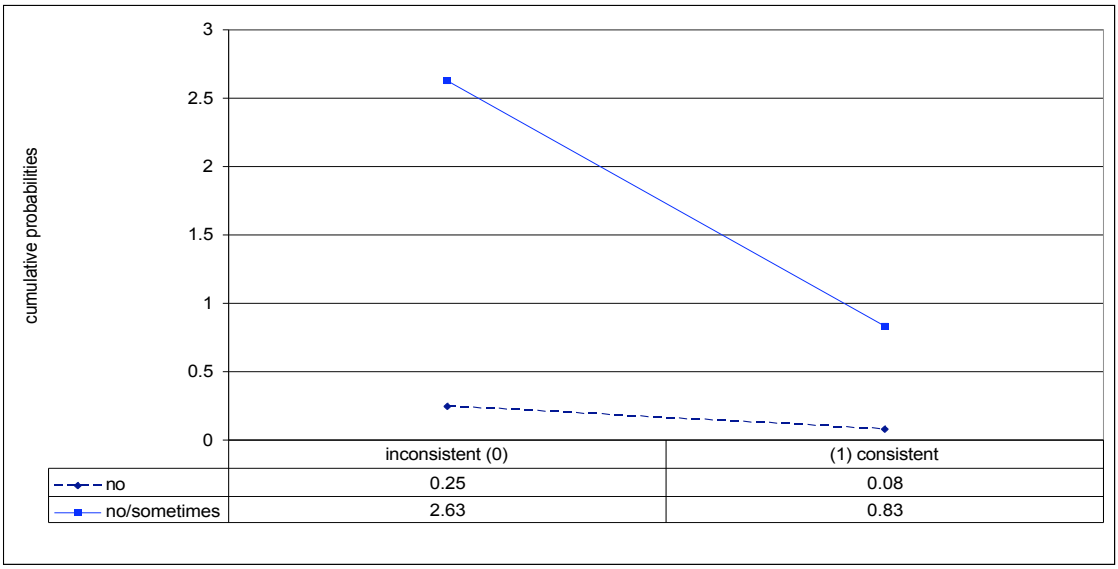

Figure 4.4 Effect of consistency on manic prodrome identification (Cumulative probabilities)

Figure 4.5 examines the probability for the individual values of the DV. As above this figure demonstrates that the probability of being able to identify symptoms is higher for participants who experienced consistent symptoms.

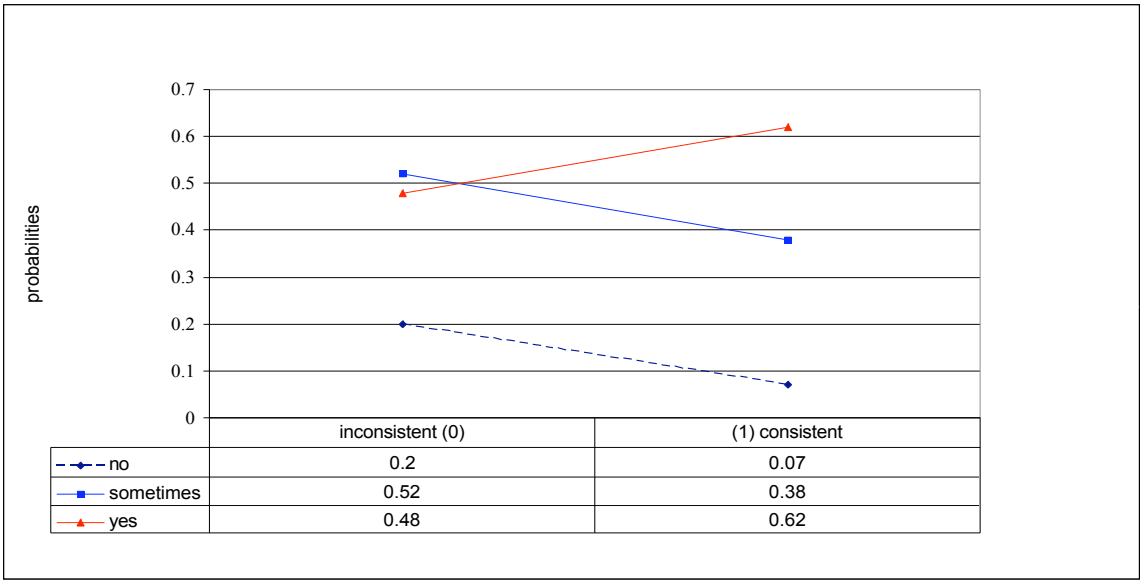

Figure 4.5 Probabilities for each value of the DV (participants' perception of their ability to identify manic prodromes)

The PVs self-efficacy and consistency of manic prodromes were significantly related to the participants' ability to identify manic prodromes. The two PVs were therefore entered into the logistic ordinal regression model in order to determine if participants who experience consistent prodromes are more able to identify manic prodromes, when self-efficacy score is entered as a covariate. Table 4.21 provides a summary of the results from this analysis.

Table 4.21 Summary of results from logistic ordinal regression 1(b)

						95% confidence interval	
PV	Estimate	Std. Error	Wald (d.f.)	Sig	b	Lower bound	Upper bound
Self-efficacy	1.007	.033	1.68 (1)	.196	2.74	1.22	6.14
Consistency	.042	.412	6.08 (1)	.014	1.04	.98	1.11

The results show that consistency of symptoms and ability to identify manic prodromes is positively significantly related when controlling for self-efficacy. When controlling for consistency of symptoms, self-efficacy is no longer statistically significant. The OR for consistency of symptoms is 2.74: the OR is higher after self-efficacy was entered into the model as a covariate. The odds of not being able to identify manic prodromes were 2.74 times less for participants who stated they experience consistent manic prodromes.

4.5.1.1.3 Ordinal logistic regression 2: Ability to identify depressive prodromes

The second logistic ordinal regression analysis was carried out to examine the relationship between age, gender, consistency, and self-efficacy with reference to participants' ability to identify depressive prodromes. The results are summarised in Table 4.22.

Table 4.22 Summary of results from ordinal logistic regression 2

						95% confidence interval	
PV	Estimate	Std. Error	Wald (d.f.)	Sig	Exp (B)	Lower bound	Upper bound
Age	-.01	.01	1.22 (1)	.27	.10	.98	1.01
Gender	.69	.39	3.04 (1)	.08	.20	.92	4.31
Consistency	1.11	.41	1.90 (1)	.001	.65	.48	.87
Self-efficacy	-.02	.01	1.10(1)	.22	.99	.96	1.00
Type of help	-.19	.45	.055 (1)	.86	.90	.37	2.16

Each PV was entered individually into the model

The PVs type of help and gender were not significant. When the PV 'consistency' was entered into the ordinal regression a significant positive slope was found: this indicated that participants who experienced consistent symptoms were more able to identify depressive prodromes. Figure 4.5 provides a summary of the estimated logits for 'unable to identify' prodromes compared with 'sometimes able' and 'able to identify' prodromes in relation to consistency of depressive prodromes.

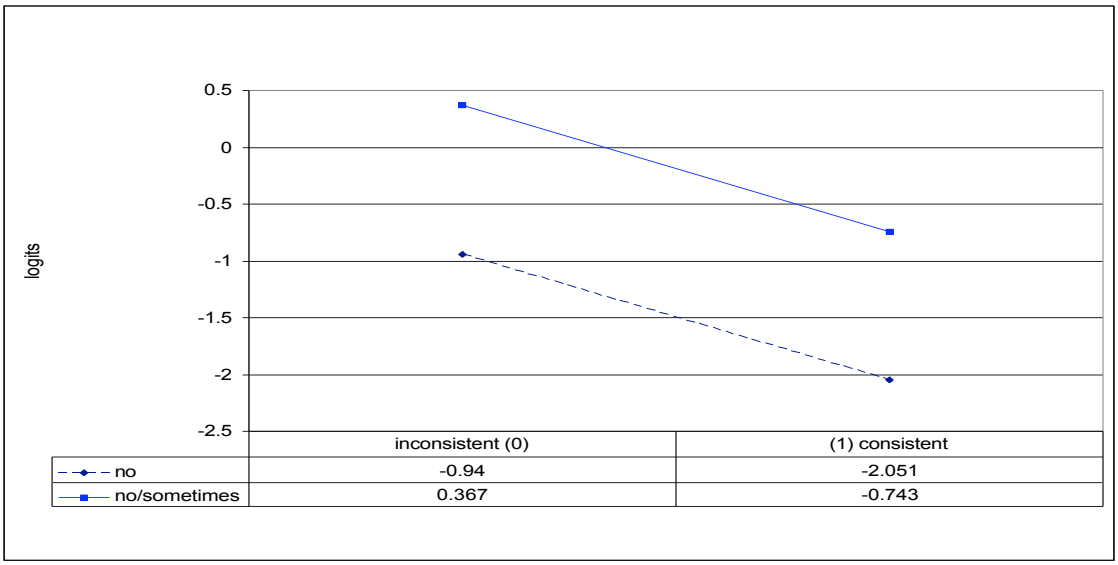

Figure 4.6 Effect of prodromal consistency on participants' ability to identify depressive prodromes (Logits)

Figure 4.6 demonstrates that the cumulative logits of being able to identify depressive prodromes are higher for participants with consistent symptoms.

Figure 4.7 provides a summary of the cumulative odds for ability to identify depressive prodromes in relation to consistency of symptoms.

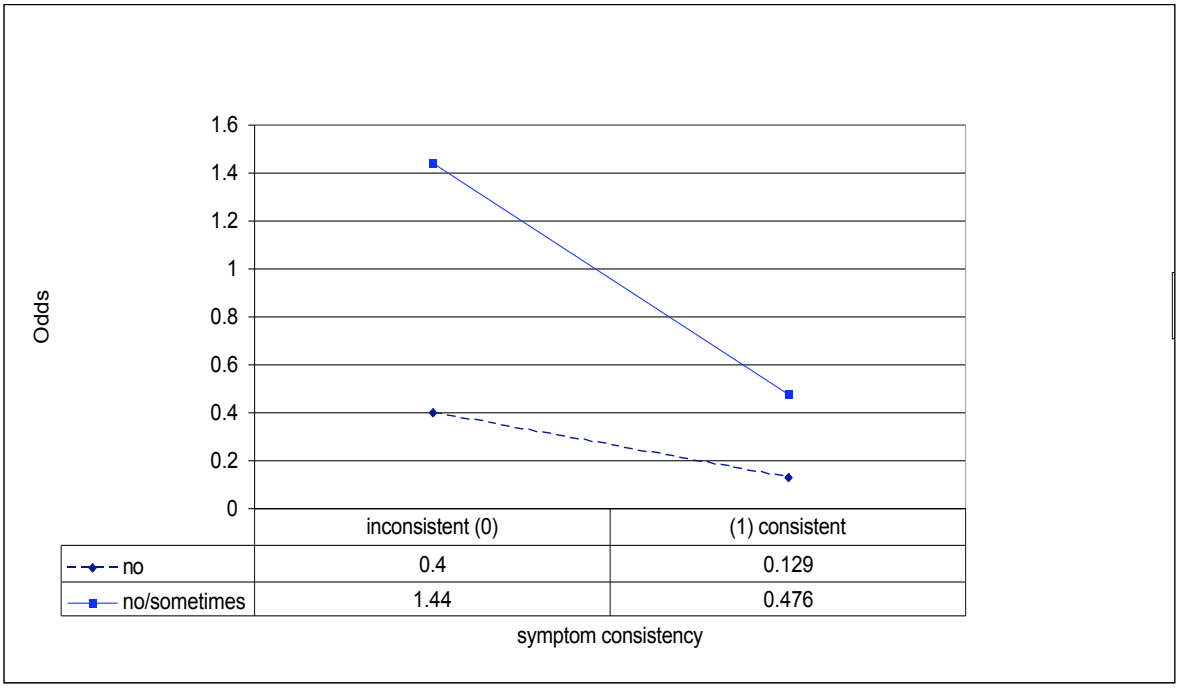

Figure 4.7 Effect of consistency on manic prodrome identification (Odds)

Figure 4.7 demonstrates that the estimated odds for being unable to identify prodromes (compared to sometimes, able to identify) and the odds of being unable to or sometimes able to identify (compared to being able to identify prodromes) are lower for participants who experienced consistent symptoms.

Figure 4.8 provides a summary of participants' ability to identify depressive prodromes in relation to cumulative probabilities.

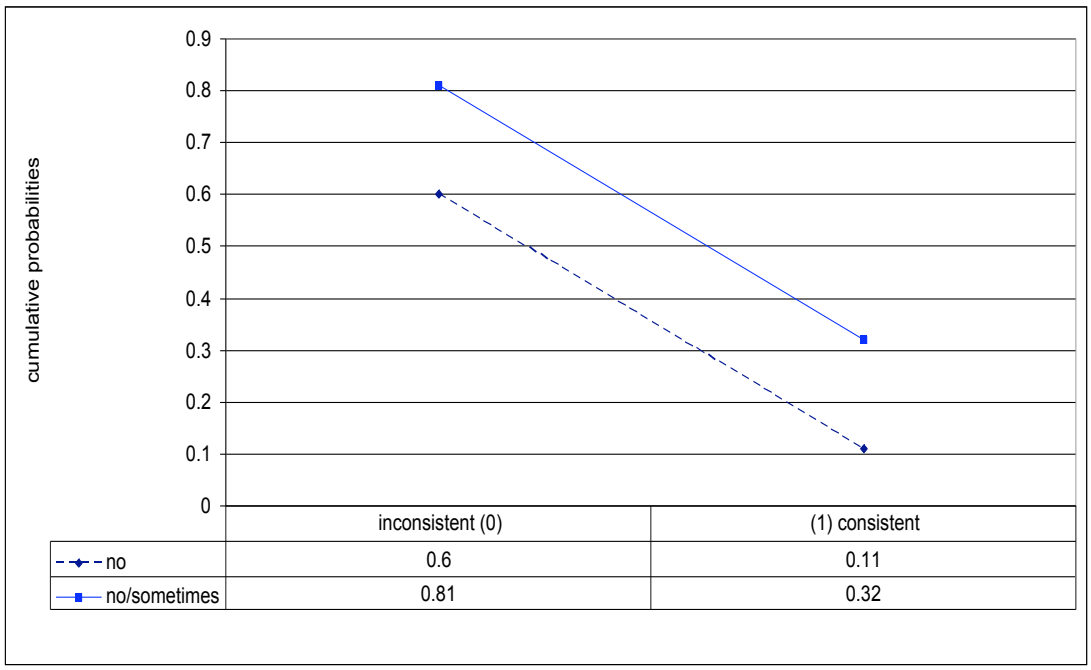

Figure 4.8 Effect of consistency of manic prodrome identification (Cumulative probabilities)

Figure 4.8 figure also shows that the probability of being unable to identify depressive prodromes is lower for participants who experienced consistent symptoms.

Figure 4.9 provides a summary of the probability for the individual values of the DV. As above, this figure demonstrates that the probability of being able to identify symptoms is higher for participants who experienced consistent symptoms.

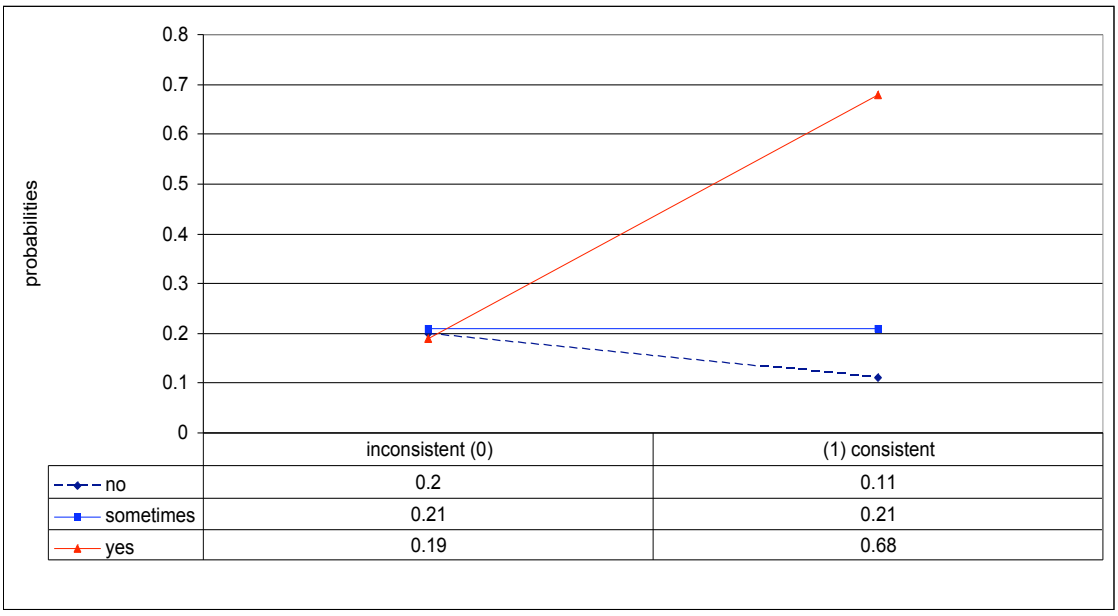

Figure 4.9 Probabilities for each level of the DV (participants' perception of their ability to identify depressive prodromes)

4.5.1.1.4 Ordinal logistic regression 3: Participants' view of their ability to manage manic prodromes

Table 4.23 provides a summary of the logistic ordinal regression for the participants' view of their ability to manage prodromes in relation to perceived consistency of prodromes and general self-efficacy scores.

Table 4.23 Summary of results from logistic ordinal regression 3

						95% confidence interval	
PV	Estimate	Std. Error	Wald (d.f.)	Sig	Exp (B)	Lower bound	Upper bound
Consistency	.502	.391	1.65 (1)	.199	1.65	.77	3.56
Self-efficacy	.032	.055	10.27(1)	.001	1.03	1.01	1.05

Each PV was entered individually into the model

The ability to identify manic prodromes was positively associated with self-efficacy. The sign of the slope is positive, therefore indicating that higher self-efficacy scores

were associated with ability to identify manic prodromes. When the OR = 1.03: for a standard deviation decrease in self-efficacy, the odds of not being able to manage prodromes increase by a factor of 1.03.

4.5.1.1.5 Logistic ordinal regression analysis 4: Participants' view of their ability to manage depressive prodromes

Table 4.24 provides a summary of the results from the fourth logistic regression analysis.

Table 4.24 Summary of results from logistic ordinal regression 4

						95% confidence interval	
PV	Estimate	Std. Error	Wald (d.f.)	Sig	Exp (B)	Lower bound	Upper bound
Consistency	.58	.39	2.20(1)	.14	1.78	.83	3.81
Self-efficacy	.018	.01	2.43 (1)	.12	1.02	.99	1.04

Each PV was entered individually into the model

Consistency of prodromes and self-efficacy score were not significantly related with the DV ability to manage depressive prodromes.

Results from the three stages of the analyses are reviewed in the discussion section in relation to the research hypotheses and the research questions. The results are also considered in relation to previous research findings, in particular results regarding the effect of gender, consistency of prodromal symptoms experienced, participants' ability to identify prodromal symptoms when they first present and whether help from significant others has an impact on participants' perception of their ability to identify and manage prodromal symptoms. Information relating to the association between the participant's perception of their ability to identify and manage prodromal symptoms is also considered in relation to self-efficacy.

5.0 DISCUSSION

5.1 Overview

The present study used an exploratory quantitative approach to investigate if individual, disorder, and treatment-related variables were associated with the participants' perception of their ability to identify and manage prodromal symptoms. Prior to discussing the key findings, the results concerned with the demographic and clinical profiles of the participants are reviewed. The main findings are then summarised and interpreted in relation to previous research, the research hypotheses, and the *a priori* research questions. This information is followed by a critique of the current study in which the suitability of the methodology is considered. The clinical implications of the findings are then presented. Lastly, potential future research will be considered.

5.2. Demographic and clinical profile of participants by recruitment source

Participants from the three recruitment sources did not significantly differ with regards to clinical and demographic-related variables. The individuals with a rapid cycling specifier experienced significantly more manic and depressive episodes compared to the bipolar I and II disorder participants. This result was expected as individuals are given a rapid cycling specifier when they experience four or more episodes in a 12-month period (DSM-IV, 1994). No other significant differences were observed for diagnosis type.

5.3 Summary and interpretation of the research findings

5.3.1. The role of self-efficacy

The findings concerned with general self-efficacy will be discussed in relation to **research hypothesis 1**: Self-efficacy will be positively associated with an individual's perception of their ability to identify and manage manic and depressive prodromes.

No significant relationships were found between general self-efficacy scores and the following variables: gender, number of episodes experienced, and current mood state. General self-efficacy was, however, significantly negatively associated with level of psychosocial input received from mental health services. The number of relapses

experienced may be a contributory factor for the observed low self-efficacy scores as individuals who received higher levels of support may have experienced more relapses. The results, however, showed that there was no relationship between the number of episodes experienced and the level of psychosocial input received. An alternative explanation is that help from services has a detrimental impact upon individual's perception of their ability to cope independently. Generalised self-efficacy refers to a global confidence in one's ability across a range of demanding settings (Schwarzer, 1993). If an individual is receiving increased input from services this may indicate to them that they have failed to cope with their condition; this perception of being unable to cope could result in a lower sense of general self-efficacy.

There was a significant association between participants' ability to identify and manage manic prodromes and higher general self-efficacy scores. This effect was found for the ability to identify and manage depressive cognitive and behavioural prodromal symptoms. These results indicate that self-efficacy may be associated with prodromal monitoring of cognitive and behavioural prodromes but not affective prodromes.

The results show the benefits of examining participants' views of their ability to identify and manage different types of prodromes. It is possible that for depressive prodromes, individuals benefit from seeing the type of symptoms that can be experienced; this may serve as a prompt that helps individuals to recall their experiences of identifying and managing depressive prodromal symptoms.

Research in this area highlights the influential nature of current mood state for individuals with bipolar disorder. For example, self-esteem is thought to be associated with mood state and research demonstrates that increasing levels of negative self-esteem predict relapse particularly into bipolar depression (Johnson *et al.*, 2000). Furthermore, as mood states such as depression, are associated with negative dysfunctional attitudes and negative attributional styles (Reilly-Harrington *et al.*, 2010) one would expect that participants identified as depressed (from their responses to the ISS) would have lower

self-reported general self-efficacy scores. This, however, was not found in the present study. Furthermore, the research findings collectively demonstrated that mood state was not associated with participants' perception of their ability to identify or manage prodromal symptoms.

One potential explanation for the current findings is that self-report approaches do not reveal negative feelings about individuals' ability to cope (as measured by the General Self-Efficacy Scale, GSES, Schwarzer & Jerusalemm 1995). For example, research demonstrates that bipolar participants show high levels of social desirability and social conformism (Pardoen *et al.,* 1993; Scott *et al.*, 2000) and it is therefore questionable if explicit measures lead to socially desirable responses. A review of the data, for the GSES, however, revealed that a normal distribution of responses was found: if the participants were all responding in a socially desirable manner one would expect the data to be positively skewed as all the participants would be rating their ability to cope as high.

An alternative explanation is that general self-efficacy may not affected by mood state. Perceived self-efficacy is characterised as being competence-based, prospective, and action-related (Bandura, 2002); it is possible that self-efficacy is determined by previous experiences and examples of times that the individual has coped. Furthermore, as general self-efficacy is associated with the individuals' ability to cope in a number of domains, examples of coping that are not explicitly related to their experience of bipolar disorder may also contribute to participants' judgements of their efficaciousness (Luszcynska *et al.*, 2005). Therefore, with reference to prodromal monitoring, individuals may benefit from concrete examples of times that they have managed their symptoms and other difficulties in their lives.

As individuals with bipolar disorder experience considerable changes in mood state it is helpful to highlight a construct that may not be influenced by mood state. Furthermore, generalised self-efficacy is implicated in self-management healthcare practices as

individuals with stronger self-efficacy are more likely to engage in healthy behaviours, to maintain them, and to recover from perceived health-related set backs (Luszczynska *et al.*, 2005). Further research, however, is required to assess if the current findings can be replicated with another sample of individuals with bipolar disorder.

Collectively the results show that general self-efficacy is associated with participants' ability to identify prodromal symptoms and the management of manic prodromes and behavioural and cognitive depressive prodromal symptoms. The research **hypothesis 1** is therefore accepted as self-efficacy was viewed as being associated with participants' view of their ability to identify and manage prodromal symptoms.

5.3.2. Disorder-related support from significant others

The findings regarding the impact of help from significant others in identifying and managing prodromal symptoms will be discussed in relation to **hypothesis 2:** Social support, in relation to help from a significant other in managing bipolar disorder, will be positively associated with an individual's belief that they can identify and manage prodromal symptoms.

Social support can be defined as helpful actions performed by significant others. Social support is generally viewed as beneficial for the course of bipolar disorder (e.g. reduction in number of relapses (Cohen *et al.*, 2004; Johnson *et al.*, 1999; Kulhara *et al.*, 1999). No significant relationships, however, were found when the participants' perception of their ability to identify and manage prodromal symptoms was examined in relation to whether or not they received help from a significant other.

Social support can provide different functions such as emotional concern (e.g. empathy, sympathy), instrumental aid (e.g. actions that help individuals to fulfil obligations), information, and appraisal (e.g. personal feedback) (House, 1981, cited in Romans & McPherson, 1992). As social support can serve different functions the type of support that participants received from significant others was categorised based on qualitative

information provided by the participants. Therefore, help from significant others was categorised as either emotional/practical support or disorder-related support. Categorising help in this manner enabled the impact of different types of support on participants' perception of their ability to identify and manage prodromes to be examined.

The findings indicated that disorder-related support is associated with participants' view of their ability to identify manic and depressive prodromal symptoms. When the participants' perception of their ability to manage prodromal symptoms was examined in relation to type of help received, no significant effect of help was found. This may be associated with the type of psychoeducational input that significant others receive from mental health professionals. For example, while relapse prevention plans are discussed with significant others during psychosocial interventions such as Family-Focused Therapy (Simoneau, *et al.*, 1999) the intervention may focus on service-related help such as contacting mental health professionals. Therefore, the significant other may not be perceived as actively helping them to manage their prodromal symptoms.

A further potential explanation involves how individuals may feel about asking or receiving help from significant others in managing prodromal symptoms. For example individuals who feel stigmatised by their disorder may find it difficult to seek support (Lam *et al*., 1999). In addition individuals who have perfectionist tendencies (which can be viewed as a common dysfunctional assumption among individuals with bipolar disorder) may have concerns about revealing that they need help to manage their illness as they may worry this will be construed as a sign of weakness.

An alternative explanation may involve how prodromal management is conceptualised by the individual with bipolar disorder. It is possible that prodromal management is viewed as an internal process and therefore based on the individual's ability to manage on their own and not influenced by external factors (i.e. help from significant others). This possibility is supported by research that shows that individuals with bipolar

disorder show higher levels of sociotrophy (interpersonal independence) and dysfunctional attitudes that are related to the need for social approval and perfectionism (Scott & Pope, 2003). For example, it is possible that autonomous personal beliefs lead individuals to disregard input from significant others regarding prodromal management.

While many benefits of social support have been empirically evidenced, the potential detrimental effect of social support, characterised by help from a significant other, has not been examined in this population. The need for social approval may result in help received from significant others being viewed negatively. For example, it is outside normal relationship dynamics for a loved one to become a 'carer'. The Significant Others Scale (SOS, Power *et al.*, 1988) was used to assess the participants' perception of the actual emotional and practical support they received from significant others. The SOS also provided information on the participants' ideal level of support.

The findings from the questionnaire provide support for the view that some aspects of support may be viewed negatively. In particular, the results showed that the participants wanted to have more emotional support from significant others and less practical support from significant others. This finding provides support for the view that individuals may view certain components of support in a negative manner. It is possible that the research sample views emotional support as a normal part of a loving relationship, whereas practical support may be associated with needing help to manage with day-to-day tasks as a result of having bipolar disorder.

When considering the results in relation to the **hypothesis 2** it can be concluded that a significant effect of social support was found for participants' perception of their ability to identify prodromal symptoms but not their perception of their ability to manage prodromal symptoms. The research hypothesis was therefore rejected.

5.3.3. The impact of disorder-related psychosocial input from mental health services

Research findings associated with the impact of psychosocial input for identifying and managing prodromal symptoms will be explored in relation to **hypothesis 3:** Previous and current psychosocial input will be positively associated with participants' perception of their ability to identify and manage prodromal symptoms.

When the impact of psychosocial input (from mental health services) was reviewed in relation to participants' perception of their ability to identify and manage prodromal symptoms, no significant associations were found. As above, the finding may be associated with prodromal management being viewed as an internal process that is not influenced by external factors. This postulation receives support from the finding that psychosocial input was negatively associated with self-efficacy scores: this indicates that increased input from services is related to lower self-efficacy scores and may be associated with a reduction in participants' perception of their ability to cope with difficult situations.

When the role of psychosocial input was reviewed in relation to prodromal symptom type (i.e. cognitive, affective, and behavioural), psychosocial input was positively associated with the ability to identify manic and depressive behavioural prodromes. Behavioural symptoms tend to present externally and are therefore more apparent than affective or cognitive prodromes when they first appear; consequently they may be more open to interventions provided by mental health professionals. As specific information on the type of support provided by mental health professionals was not obtained in the current study, it is not possible to explore this explanation in more detail.

Collectively the results indicated that, with the exception of manic and depressive behavioural prodromal symptoms, input from psychosocial services does not help participants to identify and manage prodromal symptoms. Research **hypothesis 3** is therefore rejected and the null hypothesis is accepted.

5.3.4.Additional factors associated with participants' experience of prodromal symptoms

As the study was exploratory in nature a number of variables were analysed in relation to the participants' experience of prodromal symptoms and their ability to identify and manage these symptoms. Key research findings that enable the following **research question** to be examined are summarised and interpreted below: Are the following factors associated with participants' perception of their ability to identify and manage prodromal symptoms: time since diagnosis, gender, age, number of episodes experienced, and current mood state?

5.3.4.1 Time since diagnosis

The variables time since diagnosis and age were significantly associated with each other. Research has identified an average age of onset for bipolar disorders (e.g. Goodwin & Jamison, 2007); therefore a positive linear relationship would be expected when the relationship between these two variables is examined. A significant association was also found for age and number of manic episodes experienced; this result was not found for number of depressive episodes experienced. Individuals tend to experience more manic than depressive episodes during the course of this illness (ten Have *et al.,* 2002) therefore a linear relationship would be expected with regards to the experience of manic episodes.

5.3.4.2 Age

A moderate positive association was found for age and level of psychosocial input received. Research shows that there is a positive linear relationship between number of previous episodes and relapse rates (Maj, 1999), therefore participants with a longer history of bipolar disorder may experience more frequent relapses and hence require more psychosocial input. When the type of prodrome experienced was reviewed in relation to age a negative significant correlation was found for age and ability to identify manic and depressive affective prodromes. This finding is difficult to interpret as age was not associated with the other types of prodromes. It is possible that there is

something intrinsically difficult about distinguishing positive or negative thought patterns when these types of symptoms have been experienced for a considerable length of time. Furthermore, with reference to depressive affective prodromes, with increased experience of subsyndromal symptoms individuals may find it harder to distinguish between this type of symptom and prodromal symptoms.

5.3.4.3 Gender-related findings

Data from the Prodromal Experience Questionnaire indicated that males and females have different experiences of bipolar disorder with reference to their beliefs associated with their ability to identify depressive prodromal symptoms. Female participants perceived that they were better at identifying affective, cognitive, and behavioural depressive prodromal symptoms in comparison to the male participants. While there was a trend for females to be better at identifying manic prodromal symptoms this result was not significant. In addition, no effect of gender was observed when participants' perception of their ability to manage manic and depressive prodromal symptoms was examined.

The gender-related difference may be understood in relation to gender-related differences observed in illness management practices. Findings from physical health care studies indicate that females are more likely to engage in preventative health care practices in comparison to males (e.g. Janda *et al.*, 2004; Miller *et al.*, 1996). Furthermore, males are thought to be less convinced of the value of preventative health care practices (e.g. Evans *et al.*, 2005). Females may therefore be more likely to engage in practices that help them to identify depressive prodromal symptoms.

Verbrugge (1985) highlighted three concepts associated with illness management that help to explain the observed gender differences in preventative health care practices: perception, evaluation, and action. With regards to the concept of 'perception', he postulated that females are more sensitive to body discomfort due to childhood socialisation. With reference to 'evaluation' he proposed that females are more apt than

males at labelling their experiences of physical illness, as males may actively ignore symptoms of physical illness because acknowledging symptoms may be viewed as emasculating. Lastly, with reference to 'action' Verbrugge (1985) hypothesised females determine early on that their symptoms warrant care.

When viewing prodromal identification as an illness management approach, the gender-related differences observed with male health care practices may account for the observed differences in the male and female participants' ability to identify depressive prodromes. One would assume, however, that if the observed difference was accounted for by health care practices alone, a similar pattern of results would be found for manic symptoms and that females would believe that they are more able to identify manic prodromes. Within this study, however, no significant gender-related differences for manic prodromes were observed.

An alternative explanation that may account for the fact that differences were only observed for depressive prodromal identification, involves emotional regulation gender differences. Emotional regulation is defined as the process of attending to one's emotions, being clear about them, and being able to implement strategies to repair negative emotional mood states (Thayer *et al*., 2003). Females have been shown to report more depressive symptoms than males (Nolen-Hoeksema, 2001), to report higher levels of emotional awareness (Barrett *et al.*, 2000) and to report greater attention to emotions than males (Thayer, *et al.*, 2003). Research on emotion perception has also shown that females perform better than males in both detecting and expressing emotions (Thayer & Johnsen, 2000). The effect of gender on emotion perception has also been observed in psychiatric samples (Bozikas, *et al.*, 2006; Sundet, *et al*., 2007).

Several explanations have been posited in order to explain why females report more depressive symptoms than males such as biological explanations (e.g. ovarian hormones), social and cultural issues (e.g. women's lower social status) (Thayer *et al.*, 2003) and psychological factors (e.g. females' tendency to ruminate) (Nolen-Hoeksema,

et al., 1999). With reference to rumination, females are assumed to use rumination as a coping style; it is hypothesised that it is this very coping style that serves to increase their ability to identify depressive symptoms (Nolen-Hoeksema *et al.*, 1993). If increased sensitivity to depressive symptoms is associated with the coping strategy of rumination, then this may explain why a gender-effect of identification of manic symptoms was not observed; it is possible that rumination does not serve to highlight symptoms associated with a switch to a manic mood state.

As stated above, a gender-related effect was not observed for participants' perception of their ability to manage prodromal symptoms. Emotional regulation research may also explain why females do not perceive that they are more able to manage prodromal symptoms when compared to male participants. As previously noted, emotional regulation can be viewed as consisting of three components: being able to attend to one's emotions, being clear about one's emotions, and being able to implement strategies to repair negative emotions. While females may be better than males at attending to and clarifying emotions, it is possible that there are no gender differences with regards to coping strategies for repairing or managing negative emotions. For example, research conducted by Thalyer *et al.* (2003) concluded that while women were more able to attend to emotions they were less able than males to utilise effective strategies to manage these negative emotional states.

Thalyer *et al.*, (2003) proposed that females do not implement effective 'repair' strategies due to their tendency to ruminate. While rumination serves to increase female's ability to attend to negative emotions, rumination is viewed as an ineffective repair strategy. Emotional regulation research may therefore help to elucidate the incongruent result concerning gender-related differences in participants' view of their ability to identify prodromal symptoms and no effect of gender concerning participants' ability to manage prodromal symptoms.

5.3.4.4 Number of episodes experienced

A negative correlation was found between the number of manic episodes experienced and participants' perception of their ability to manage manic prodromal symptoms. This finding may be accounted for by the individuals' view of their ability to cope with manic prodromes in relation to the linear experience of episodes. Research conducted by Goosens *et al.,* (2008) found that patients who experienced 10 or more acute episodes of depression or manic during the course of their disorder reported the use of passive coping styles. This could indicate that with increased experience of episodes self-management approaches are less likely to be used. This finding was not, however, observed for depressive prodromal symptoms. The available data do not enable this possibility to be explored in more detail.

5.3.5. Issues associated with the polarity of prodromal symptoms

The findings associated with the polarity of prodromal symptoms are discussed in relation to the following **research question**: Is the polarity of the prodromal symptom associated with the participants' perception of their ability to identify and manage manic and depressive prodromal symptoms?

Previous research (e.g. Jackson *et al.*, 2003; Lam & Wong, 1997; Sierra *et al.*, 2008) highlights that patients find it easier to identify manic prodromes in comparison to depressive prodromes. Manic prodromes are thought to differ qualitatively from individual's day-to-day experiences; it is this qualitative difference that is attributed to manic prodromes being more readily identified by patients. Whereas it is proposed that early symptoms of depression may be less overt and therefore less easily recognised (e.g. Jackson *et al.*, 2003). The results from the Prodromal Experience Questionnaire indicated that the sample viewed depressive prodromal symptoms as being easier to identify in comparison to the manic symptoms; this finding is in direct contrast to existing research evidence regarding participant's experience of prodromes by polarity.

A possible explanation for the observed finding may involve the methods used to gain information on participant's experiences of prodromes. In the current study a checklist of items was used (the Prodromal Experience Questionnaire). Research conducted by Lam and Wong (1997) in which participants were asked to spontaneously recall their experiences of prodromal symptoms resulted in a mean of three manic and two depressive prodromes being recalled. Whereas research conducted by Smith and Tarrier (1992) in which a 40-item checklist of prodromes was used resulted in a mean of 15 manic items and 11 depressive items being identified. It is possible that a pre-determined checklist measure has resulted in participants endorsing items that are similar to those experienced in full-blown episodes, to subsyndromal symptoms, and or transient mood states.

While it is possible that the measure used has served to escalate participants' recall of depressive prodromes, one would still expect to see a greater rate of manic prodromes endorsed on the checklist. Furthermore, when participants were asked to state if they believed they were able to identify manic and depressive prodromal symptoms (this question was not directly linked to specific prodromal symptoms) a non-significant difference was found between participants' view of their ability to identify manic and depressive prodromes; while this difference was not significant, based on previous research, one would expect that participants would recall significantly more manic prodromes.

An alternative possibility is that there were more depressed participants in the sub-sample of participants who completed the Prodromal Experience Questionnaire. A depressed mood state may have caused the participants to over-identify with the depressive prodromes that were listed, as participants may have been cognitively biased towards the depressive stimuli. A review of the participant's mood state (as determined by the ISS) showed that there were more depressed participants in comparison to the euthymic, manic, or mixed mood state in the sub-sample. The higher prevalence of

depressed participants in the sub-sample may account for the increased rate of depressive prodromes that were identified.

5.3.6. Type of prodromal symptoms

The following information will be discussed in relation to the **research question:** Are types of prodromal symptoms (i.e. cognitive, affective, and behavioural) associated with the participants' perception of their ability to identify and manage manic and depressive prodromal symptoms?

When the participants' experience of prodromal symptoms by type (i.e. affective, cognitive, and behavioural) was reviewed, the results indicated different factors were associated with the different types of prodromal symptoms. For example, age was negatively associated with participants' view of their ability to identify manic and depressive affective prodromal symptoms but not the cognitive and behavioural prodromal symptoms.

Collectively the results indicated that different factors may contribute to participants' perception of their ability to manage and identify cognitive, behavioural, and affective prodromal symptoms. Therefore, it may be beneficial to view prodromal symptoms by type in addition to polarity when working with individuals. This issue is explored in more detail with reference to clinical implications in section 5.6.

5.3.7. Prodromal monitoring and identifiable and consistent symptoms

The following research questions are relevant to the information discussed in this section:

Research question: Does the ability to identify prodromal symptoms when they first present have an impact on participants' perception of their ability to identify and manage prodromal symptoms?

Research question: Does the consistency of prodromal symptoms (across episodes) have an impact on participants' perception of their ability to identify and manage prodromal symptoms?

The results indicated that participants who experienced consistent prodromal symptoms were more confident in their ability to identify prodromal symptoms. In addition, the findings showed that being able to identify depressive prodromes when they first present and consistently experienced prodromes increase individuals' perception of their ability to manage depressive prodromes.

The chronic nature of bipolar disorder means that it occurs across time. Recurring prodromal symptoms may serve to familiarise the individual with their relapse signature and help the individual to understand that there are some elements of this disorder that they can expect to experience. Furthermore, an individual's prior experience with symptoms can positively influence how current symptoms are managed (e.g. Stoller *et al.*, 1995). Therefore, it is likely that perceived consistency of prodromal symptoms would serve to increase participants' view of their ability to identify and manage prodromal symptoms.

The results, however, indicated that consistent prodromal symptoms do not serve to increase an individuals' view of their ability to manage manic prodromal symptoms. This may be because manic symptoms are viewed as difficult to manage. This mood state is viewed by some individuals as pleasant and therefore consistent symptoms would not serve to change this perception of mania and thereby symptoms consistency would not assist with the management of these types of prodromal symptoms.

The current research has served to highlight individual, disorder, and treatment-related variables that are associated with prodromal monitoring and management. Prior to considering the clinical implications of the current findings, the methodology used in the study is critiqued below.

5.4 Critique of the research study

In order to highlight strengths and limitations associated with the current research, information relating to the sample size, recruitment process, the measures used, how variables were defined, the retrospective research approach, and the statistical analysis are reviewed in the following sections.

5.4.1 Power analysis

An *a priori* power analysis was performed to inform optimal sample size for the primary analyses. Based on information provided by Cohen (1992), a sample of 91 participants was required to achieve a medium effect size at a significance level of 0.05 (for an ordinal regression analysis with five predictor variables). As the sample consisted of 101 participants, adequate power was therefore achieved.

5.4.2 The research sample

Research that examines prodromal monitoring has been criticised for excluding participants with bipolar II disorder as this can limit the extent to which the results can be generalised in clinical settings (Mantere *et al.*, 2008). The present research addressed this limitation by including both bipolar I and II participants.

A further criticism of this research area involves the exclusion of participants with co-morbid diagnoses. A high percentage of individuals with bipolar disorder have co-morbid diagnoses (e.g. McElroy, *et al.*, 2001); consequently, excluding individuals with a co-morbid diagnosis from research has an impact upon the extent to which the research findings can be extrapolated to clinical settings. While information on co-morbidity was not directly sought in this research, co-morbidity was not used as an exclusion criterion. As information on co-morbid diagnoses was not obtained it is not possible to explore the relationship between co-morbid diagnoses and features associated with prodromal monitoring.

While information on prodromal monitoring, in the context of self-management, was given to participants in written and oral formats, no formal measure of participants' experience or understanding of prodromal monitoring was used in the study. It is therefore possible that some of the participants did not fully understand what prodromal symptoms were nor had experience in actively trying to identify and manage these symptoms. Some individuals with bipolar disorder may experience difficulties distinguishing between subsyndromal and prodromal symptoms (Lam & Wong, 1997); therefore when providing information on their experience of prodromal symptoms it is possible that some participants were reflecting on their experiences with subsyndromal symptoms. Participants had several opportunities to ask questions about the research: none of the participants sought clarification about the definition of prodromal symptoms. As participants did not ask for further clarification, this may indicate that the sample had a good understanding of prodromal symptoms.

5.4.3 The design and research measures

5.4.3.1 The appropriateness of self-report measures for individuals with bipolar disorder

A key strength of the current study involves the fact that individuals' perception of their experience of prodromal symptoms was sought. To date, the majority of research in this area has examined prodromal management in relation to objective outcome measures such as relapse rates and hospitalisation. While this information serves to show that this approach can be effective for reducing rates of relapse, it does not provide information on the mechanisms involved in identifying and managing prodromal symptoms. While it is therefore beneficial to gain information from patients it is necessary to consider the methods used to obtain this information in order to determine if the approach was appropriate for individuals with bipolar disorder.

Self-report measures were used to obtain relevant information in the current study. Self-report questionnaires may have limited usefulness in patients with diminished concentration. Individuals with bipolar disorder may display deficits on a range of

neuropsychological tasks in both acute and euthymic phases of the illness (Emilien *et al.*, 2007); consequently, the suitability of self-report measures with this population needs to be considered.

Observations of participants completing the questionnaires indicated that they did not find the process cognitively demanding. Furthermore, a high response rate indicates that the questionnaires were not perceived as too challenging to complete. It is worth noting that seven participants withdrew from the study following information about the questionnaires being provided by the researcher. It is possible that these individuals self-selected themselves out of the study due to issues associated with fatigue and concentration difficulties.

5.4.3.2 Retrospective data collection

Completion of the questionnaires was reliant on retrospective information; this type of recall can be open to bias (Nhiwatiwa, 2003). The study, however, was concerned with participants' perception of their ability to cope with prodromal symptoms; responses therefore were reliant on participants' ability to reflect on their previous disorder-related experiences. Consequently, a prospective research design would not have been appropriate for the current study.

Participant's self-report responses were not corroborated by a significant other or by a mental health professional. With reference to the research aims, however, corroboration was not necessary as it was the participants' perception of their ability to identify and manage prodromes that was of particular interest. In addition, previous research has shown strong agreement between patients and relatives regarding recall of depressive and manic prodromes (Keitner *et al.*, 1996); this finding indicates that participants' reported experience of prodromal symptoms may be viewed as a reliable reflection of their experiences of these types of symptoms.

5.4.3.3 Questionnaire measures

With the exception of the ISS (Bauer, *et al.*, 1991) the questionnaire measures were not specifically designed for use with people with bipolar disorder. Furthermore, to date, it does not appear that the GSES has been used in research involving individuals with bipolar disorder. It has, however, been used as a measure in research with individuals with a diagnosis of schizophrenia (e.g. Vauth, *et al.*, 2007). The SOS has also been used with long-term psychiatric patients (e.g. Creswell *et al.,* 1992). The use of these measures with long-term psychiatric patients indicates that they may be appropriate for use with people with bipolar disorder. Furthermore, the measures were chosen to measure aspects that are relevant to all individuals and were not specific to a particular psychiatric condition.

The Prodromal Experience Questionnaire was designed for the purposes of this research; therefore, it has not been subjected to tests of reliability or validity. As it has not been validated for use with this population the results should be viewed with caution. The contents of the measure, however, were based on three published research studies that identified manic and depressive prodromal symptoms that are commonly experienced by individuals with bipolar disorder (Lam & Wong, 1997; Molnar *et al.*, 1988; Smith & Tarrier, 1992). It is therefore possible to view the contents of the questionnaire as valid for this population. In order to initially investigate whether this tool is appropriate for use with individuals with bipolar disorder the questionnaire should have been piloted prior to including it as a measure in the current research. Further research is required to determine whether this tool is a valid measure of individual's experience of prodromal symptoms. This issue will be discussed further with reference to future research in section 5.6.

5.4.3.4 Measures used to assess the participant's experience of bipolar disorder

It is possible that some of the measures did not adequately capture the participants' experience of bipolar disorder. For example the variable time since diagnosis is problematic as many participants stated that it took a considerable length of time to

receive a diagnosis of bipolar disorder: this is a well documented issue for people with this disorder (e.g. Ruggero *et al.,* 2010). A more accurate measure may have been to ask participants when they believed they first experienced an affective episode.

The participants were asked to provide information on the number of manic and depressive episodes they had experienced. As this question was not prefaced with a definition it is difficult to gauge if the participants were viewing the term episode in the same manner. For example, some participants may have viewed transient mood states as episodes whereas others may have viewed a relapse followed by a hospital admission as an episode. A case note review would enable accurate information regarding the number of episodes experienced to be obtained. In addition, participants could be provided with an explanation of what constitutes an episode when providing this type of disorder-related information.

The variable level of psychosocial input was used to measure participants' previous and current level of input from mental health professionals. While this measure provides information on the amount of professional input received it does not provide information on patient's treatment expectations, length of input, and overall treatment satisfaction. This measure, therefore, does not capture the participants' total experience and view of psychosocial input received and can only be viewed as a crude measure of service input received.

Issues associated with the variables time since diagnosis, number of episodes experienced, and level of psychosocial input highlight the complexities involved in quantifying an individuals' experience of bipolar disorder. The difficulties involved with the above measures may relate to the fact that while an individual's experience of bipolar disorder is subjective it is open to the influence of systemic factors. A qualitative research approach may help address such issues as this methodology would enable idiosyncrasies associated with an individual's experience of bipolar disorder to be captured.

5.4.4 Results

As the study used an exploratory approach a large number of variables were statistically examined using correlations. While correlations serve to identify significant associations this statistical test does not indicate direction of causality. The validity of inferences about cause and effect is determined by factors external to the data analysis (Shadish *et al.*, 2002); therefore, caution should be taken in inferring the causal relationships observed in this study.

As the research was exploratory, it is likely that some relevant variables were not measured. The current research aimed to examine the relationship of a range of variables and can therefore be viewed as a starting point for investigating key mechanisms involved in prodromal identification and management.

While methodological limitations of the current research have been identified, the research findings have helped to elucidate mechanisms involved in identifying and managing manic and depressive prodromes. Potential clinical implications of the current findings are discussed below.

5.5 Clinical implications

The current results could help ensure that prodromal monitoring is a targeted and specific psychological intervention that focuses on aspects that are associated with the process of prodromal monitoring. For example, the results indicated that general self-efficacy is associated with the ability to identify and manage prodromal symptoms therefore part of the therapeutic intervention could focus on increasing and monitoring self-efficacy. However, the results also indicate that increased input from services has a detrimental effect on general self-efficacy. Therefore, while working with patients the individual's existing resources and strategies for coping could be highlighted throughout therapy (e.g. the use of strategies associated with Solution-Focused Therapy as outlined

by de Shazer, 1982) in order to help patients to recognise their contribution to the therapeutic process.

The results indicated that different factors are associated with the participants' ability to identify and manage prodromal symptoms. To help to understand this result Lazarus and Folkman's (1984) coping model can be used. Within this model, coping choices are determined by two factors: the appraisal of the threat (primary appraisal) and the appraisal of one's resources to address the threat (secondary appraisal). The model posits that coping is a dynamic bidirectional process.

When this model is considered in relation to prodromal monitoring the appraisal components can be defined as: ability to identify prodromal symptoms (primary appraisal) and the ability to manage prodromal symptoms (secondary appraisal). When reviewing the explanatory function of this model in relation to coping with prodromal symptoms (i.e. the ability to identify and manage prodromal symptoms), the dynamic element becomes questionable. For prodromal monitoring the two appraisal components are best construed as separate constructs: this is due to the fact that the ability to identify and manage prodromal symptoms are not mutually exclusive. For example, the ability to identify prodromal symptoms does not guarantee that an individual will be able to manage the recognised symptoms. Therefore, the relationship between the primary and secondary appraisals may be uni-directional as the ability to manage prodromal symptoms is reliant on the ability to identify prodromal symptoms but not vice versa.

Why the ability to identify and manage prodromal symptoms is not inter-related may be due to the different factors that are involved in the ability to complete or engage in each appraisal stage. For example, the current research identified different factors associated with the ability to identify prodromal symptoms that are categorised as either manic or depressive. In addition, different factors become relevant when the polarity and the type of prodrome are considered. The findings show that different contributory factors are involved with the process of identifying and managing manic and depressive prodromes.

When this information is considered in relation to clinical implications, it serves to highlight the potential benefits of considering the different factors associated with the different stages of prodromal monitoring when working with patients.

In addition to considering clinical implications of the current research it is sensible to consider whether this approach is beneficial for all individuals with bipolar disorder. The emphasis on genetic and biological explanations can cause individuals to believe that they have no control over this disorder. Highlighting the role of psychosocial factors and introducing prodromal monitoring can give individuals a sense of control and help them to be an active agent in the management of this disorder.

While prodromal monitoring can be effective for reducing relapse rates (e.g. Perry *et al.*, 1999) several assumptions are associated with the individual's ability to engage with this approach: insight, motivation, the appropriateness of the approach, and the ability to monitor internal and external experiences. Key assumptions that are associated with successful prodromal monitoring are discussed below.

5.5.1 Key assumptions associated with prodromal monitoring

5.5.1.1 Key assumptions associated with prodromal monitoring: Insight

Adequate insight enables people to manage their illness better and can influence their day-to-day functioning (David *et al.*, 1992). A key component of insight is diagnosis acceptance. Both insight and acceptance of diagnosis are associated with an individual's ability to engage with prodromal monitoring approaches as he or she needs to play an active role in this intervention.

5.5.1.2 Key assumptions associated with prodromal monitoring: Patient perceives approach to be beneficial

"I used to be an 11 stone alcoholic having the time of my life…now I am a 13 stone depressed man. I'm not depressed because I am bipolar, I'm depressed because I'm managing my illness." (anonymous participant)

The above quotation serves to highlight potential negative aspects associated with self-management and prodromal monitoring. Prodromal monitoring requires individuals to continually monitor their mood and manage mood states through aspects such as life style changes, cognitive therapy strategies, or contact with mental health services. Regular monitoring can be problematic for some individuals. For example, in a study carried out by Colom *et al.,* (2009a) three participants reported increased anxiety, fear, and ruminations and one participant began to obsessively check his mood changes following the introduction of prodromal monitoring. A further issue involves patients becoming hyper-vigilant against transient mood states or minor changes in their moods (Schwannauer, 2004). Family members can also become hyper-vigilant toward mood changes and transient mood states: this could have a detrimental effect on family dynamics and relationships (Van Gent & Zwart, 1991).

In addition, prodromal monitoring approaches do not enable the individual to have a 'break' from bipolar disorder. For example, one participant stated:

"When I'm well I don't want to think about bipolar disorder." (anonymous)

This quotation serves to demonstrate that participants may wish to have time away for their chronic condition when they are remitted. For prodromal monitoring to be effective, however, individuals must continuously monitor their symptoms.

5.5.1.3 Key assumptions associated with prodromal monitoring: Motivation

While prodromal monitoring approaches can serve to give control to the patient, whether or not they wish to be an active agent in their illness management needs to be considered. For example, a participant questioned why he should be expected to take an active role in his mental health care:

"Self-management – so this is being put back to us again…like it is all my fault that I have bipolar disorder." (anonymous)

As stated above prodromal monitoring requires a substantial commitment and may be seen by some people as unnecessary or a as a relentless process. A factor that may increase the likelihood of engaging in this process involves individual's experience of the consequences of manic and depressive episodes. For example, one participant reported:

"I need to manage my illness…if I don't I could end up manic and in prison again" (anonymous).

For the above individual the potential costs of prodromal monitoring outweighed the potential negative consequences they associated with becoming mentally unwell. The relative costs and benefits of prodromal monitoring should be considered in relation to the patient's coping resources and for their stage of illness.

5.5.1.4 Key assumptions associated with prodromal monitoring: The ability to monitor internal and external experiences

In order to be able to monitor prodromal symptoms, individuals need to be able to re-label unusual mental events as pathological (David, 1990). It is therefore necessary to be able to monitor internal experiences: this type of monitoring is reliant on aspects such as emotional intelligence (EI, Martins *et al.,* in press) and ability to recognise cognitive and affective shifts.

Fundamental aspects of EI include the ability to recognise emotions and the ability to find ways to manage emotions. Two recent systematic reviews have demonstrated that higher EI is associated with better mental health (Martins *et al.,* in press; Schutte *et al.*, 2007). Individuals also need to learn that some mood states are transitory or reactive to external experiences and are therefore not indicative of the start of an episode. Furthermore, individuals' ability to monitor and process mood states needs to be considered prior to commencing prodromal monitoring work with the patient.

5.5.1.5 Prodromal Monitoring: Suitability of the Approach

While prodromal monitoring can be an effective approach for reducing time to relapse (e.g. Lam *et al.*, 2005) as the above information demonstrates, key assumptions associated with this approach need to be reviewed when considering the suitability of the intervention. As with any clinical intervention, how suitable it is for the individual must be considered in relation to potential benefits. This may involve considering whether the individual is ready to engage in this type of work (e.g. have they accepted their diagnosis), is motivated to monitor their mood state and behaviour on a regular basis, is able to identify shifts in cognition and affect, and is able to do so in a manner that is not detrimental to their mental health.

In addition to highlighting assumptions associated with prodromal monitoring, the above information serves to highlight additional individual-related aspects that could be considered in relation to extending the current research findings. This information is discussed below.

5.6 Future Research

This study has several limitations that could be addressed by future research. Potential research is discussed below that may enable the aforementioned limitations to be addressed.

5.6.1 Participants' perception of prodromal monitoring

While the current research aimed to elucidate key factors associated with participants' perception of their ability to identify and manage prodromal symptoms, issues associated with prodromal monitoring assumptions (as discussed above) were not investigated. When considering ability to engage in prodromal monitoring, whether the individual views this approach as valuable and one that will benefit their quality of life needs to be considered. The participants' view of prodromal monitoring (e.g. treatment expectations), their motivation to engage in this form of self-management and the extent

to which they have accepted their diagnosis were not investigated in the current research.

These individual-related factors could have a direct impact upon perception of ability to identify and manage prodromes. Measuring participants' views of the benefits of this approach, for example, would enable a further dimension to be explored – influence of perception of treatment option and view of diagnosis – in relation to participants' ability to identify and manage prodromes. In addition to the measures that were used in the current study, self-report questionnaires that enable participants' expectations of prodromal monitoring and the extent to which they accept their diagnosis, such as the Insight Questionnaire (David, 1992), could be administered to explore the impact of these factors on the participants' view of their ability to identify and manage prodromal symptoms.

5.6.2 An assessment of the validity and reliability of the Prodromal Experience Questionnaire

The Prodromal Experience Questionnaire was designed for the purposes of this research. A longitudinal design could be used to assess validity and reliability of this measure. Static information such as the type of prodromes experienced by participants could be collected on two occasions and correlational tests could assess for test-retest reliability between time 1 and time 2. Other factors, such as the individuals' perception of their ability to manage prodromal symptoms, could not be examined using a test re-test reliability statistical approach as ability to manage is not directly linked with the experience of prodromal symptoms and is open to the influence of individual-related factors such as general self-efficacy.

5.6.3. Participants' understanding of prodromal monitoring

A potential limitation of the current research involved the participants' understanding of prodromal symptoms and motivation to use this type of management approach. To address this issue, future research could involve participants who have taken part in

psychoeducation and or prodromal monitoring training packages (e.g. Wellness and Recovery Action Plan training, Early Warning Symptom identification and management programmes). Recruiting participants who have completed such courses would increase the likelihood that the participants view prodromal monitoring as a beneficial approach and wish to utilise this self-management strategy.

This proposed study could use a longitudinal design as this would enable the relationship between experience of this approach and perception of ability to identify and manage prodromal symptoms to be empirically assessed. Furthermore, variables such as general self-efficacy and experience of prodromal symptoms could be assessed at time 1 and time 2 using this type of design to assess if experience with this type of approach serves to increase the participant's view of their ability to identify and manage prodromal symptoms.

5.6.4 Measuring the benefits of focusing on individual, disorder-related factors during therapy

The current study identified the role of general self-efficacy, the ability to identify prodromal symptoms when they first present, and consistency of symptom presentation in relation to an increased ability to identify and manage prodromal symptoms. A research study that examines the effects of utilising explicit psychosocial interventions to promote the above aspects could be assessed in relation to participants' perception of their ability to identify and manage prodromes. In addition, objective outcome measures such as time to relapse, and number of days spent unwell during the study period could also be assessed. Pre- and post-measures would enable the effectiveness of teaching these skills, in addition to usual prodromal monitoring work, to be evaluated.

5.7 Consideration of the impact of the research process on the researcher's views of self-management approaches

I first became interested in self-management approaches through my clinical work with a gentleman who had a recent diagnosis of bipolar disorder. This patient believed that he

had no control over his symptoms and that the only way he could manage his disorder was through the use of medication. He found the ethos of self-management approaches enlightening and gained a sense of control over this his disorder through prodromal monitoring and associated management approaches. This clinical experience was the basis for the start of my research interest in this area.

During the course of the data collection I had the opportunity to meet with people who use prodromal monitoring as a self-management approach. Attending self–help group meetings, in particular, enabled me to recognise that while this approach can be effective for some individuals, it can also have an impact upon individual's relationships, sense of self, and quality of life. One lady I met discussed that daily mood monitoring makes her feel that she is never "well." Some individuals discussed how it feels to have loved ones monitoring their mood on a daily basis; they discussed feeling observed and judged. One individual who voiced sadness at the change in her relationship raised a particularly poignant and thought provoking point – she said that her partner had taken on the role of a carer; this included monitoring her prodromal symptoms. Several people however viewed their partner's help with symptom monitoring as invaluable. Other people discussed that prodromal monitoring helps them to stay well.

When I first starting working on this research I viewed prodromal monitoring as an empowering approach that enabled individuals to become active agents in their treatment. I had not, however, considered the emotional impact of using an approach that requires people to daily monitor their mood, behaviour, and thoughts. The use of the term 'side effects' – which is generally associated with medication – helps to summarise my new found view of prodromal monitoring: prodromal monitoring can be effective but some individuals may also experience negative effects as a result of using it. This research experience has helped me to realise that self-management interventions for chronic mental health problems are not short-term approaches but something that an individual has to use on a daily basis thereby becoming an integral part of the

individual's life. It is therefore necessary to consider the potential implications of using self-management approaches with patients with bipolar disorder.

5.8 Summary and conclusions

The current research could help inform an idiosyncratic clinical approach for helping individuals to learn how to identify and manage prodromal symptoms. While methodological limitations were identified, the findings serve to highlight that the patient's general self-efficacy, gender, experience of prodromal symptoms (with reference to polarity, type, and consistency of symptoms), type of help received from significant others, and the potential negative impact of service input should be considered when helping patients to learn to monitor prodromal symptoms. Furthermore, the current findings indicate that the two components of prodromal monitoring – identifying prodromes and managing prodromes – should be viewed as separate aspects as different factors were associated with the samples' ability to identify and manage prodromes.

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Appendix 1: DSM-IV diagnostic criteria for bipolar affective disorder

Diagnostic criteria for a Major Depressive Episode (DSM IV Criteria, APA, 1994)

For an individual to be diagnosed with major depression five (or more) of the following symptoms have to have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure. Symptoms that are clearly due to a general medical condition, or mood-incongruent delusions or hallucinations are not to be included.)

1) Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful). Note: In children and adolescents, can be irritable mood
2) Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others)
3) Significant weight loss when not dieting or weight gain (e.g., a change of more than 5 percent of body weight in a month), or decrease or increase in appetite nearly every day
4) Insomnia or hypersomnia nearly every day
5) Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
6) Fatigue or loss of energy nearly every day
7) Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
8) Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)
9) Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

B) The symptoms do not meet criteria for a Mixed Episode

C) The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning

D) The symptoms are not due to the direct physiological effects of a substance (e.g. a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism)

E) The symptoms are not better accounted for by Bereavement, i.e., after the loss of a loved one, the symptoms persist for longer than 2 months or are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation

Diagnostic Criteria for a Manic Episode (DSM IV Criteria, APA, 1994)

A) A distinct period of abnormally and persistently elevated, expansive or irritable mood, lasting at least 1 week (or any duration if hospitalization is necessary)

B) During the period of mood disturbance, three (or more) of the following symptoms have persisted (four if the mood is only irritable) and have been present to a significant degree:

1) Inflated self-esteem or grandiosity

2) Decreased need for sleep (e.g., feels rested after only 3 hours of sleep)

3) More talkative than usual or pressure to keep talking

4) Flight of ideas or subjective experience that thoughts are racing

5) Distractibility (i.e., attention too easily drawn to unimportant or irrelevant external stimuli)

6) Increase in goal-directed activity (at work, at school, or sexually) or psychomotor agitation

7) Excessive involvement in pleasurable activities that have a high potential for painful consequences (e.g., engaging in unrestrained buying sprees, sexual indiscretions, or foolish business investments)

C) The symptoms do not meet criteria for a mixed episode.

D) The mood disturbance is sufficiently severe to cause marked impairment in occupational functioning or in usual social activities or relationships with others,

necessitate hospitalization to prevent harm to self or others, or there are psychotic features.

E) The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication or other treatment) or a general medical condition (e.g., hyperthyroidism).

Diagnostic Criteria for a Mixed Episode (DSM IV Criteria, APA, 1994)

A. The criteria are met both for a manic episode and for a major depressive episode (except for duration) nearly every day during at least a 1-week period.

B. The mood disturbance is sufficiently severe to cause marked impairment in occupational functioning or in usual social activities or relationships with others, or to necessitate hospitalization to prevent harm to self or others, or there are psychotic features.

C. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication, or other treatment), or a general medical condition (e.g., hyperthyroidism).

Mixed-like episodes that are clearly caused by somatic antidepressant treatment (e.g., medication, electroconvulsive therapy, light therapy) should not count toward a diagnosis of Bipolar I Disorder.

1.2.5 Diagnostic criteria for a Hypomanic Episode

A) A distinct period of persistently elevated, expansive or irritable mood, lasting throughout at least 4 days, that is clearly different from the usual non-depressed mood.

B) During the period of mood disturbance, three (or more) of the following symptoms have persisted (four if the mood is only irritable) and have been present to a significant degree:

1) Inflated self-esteem or grandiosity
2) Decreased need for sleep (e.g., feels rested after only 3 hours of sleep)
3) More talkative than usual or pressure to keep talking
4) Flight of ideas or subjective experience that thoughts are racing
5) Distractibility (i.e., attention too easily drawn to unimportant or irrelevant external stimuli).
6) Increase in goal-directed activity (at work, at school, or sexually) or psychomotor agitation.
7) Excessive involvement in pleasurable activities that have a high potential for painful consequences (e.g., engaging in unrestrained buying sprees, sexual indiscretions, or foolish business investments).

C) The episode is associated with an unequivocal change in functioning that is uncharacteristic of the person when not symptomatic.

D) The disturbance in mood and the change in functioning are observable by others.

E) The mood disturbance not severe enough to cause marked impairment in social or occupational functioning, or to necessitate hospitalization, and there are no psychotic features.

F) The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication or other treatment) or a general medical condition (e.g. hyperthyroidism).

Hypomanic-like episodes that are clearly caused by somatic antidepressant treatment (e.g. medication, electroconvulsive therapy, light therapy) should not count toward a diagnosis of bipolar II disorder.

Appendix 2. The reason why research was excluded at stage 3 of the study eligibility review process

Study and reason for exclusion at stage 3.
1. Ball, J.R., Mitchell, Corry, J.C., Skillecorn, A., Smith, M. and Malhi, G.S. (2006). A randomised controlled trial of cognitive therapy for bipolar disorder: Focus on long-term change. *Journal of Clinical Psychiatry*, 67 (2), 277-286. Reason for exclusion: Mood monitoring also used as an intervention in the control group.
2. Bauer, M.S., McBride, L., Williford, W.O., Glick, H., Kinosian, B., Altshuler, L., et al. (2006). Collaborative care for bipolar disorder: Part I. Intervention and implementation in a randomised effectiveness trial. *Psychiatric Services*, 57 (7), 927-936. Reason for exclusion: The paper discusses proposed research.
3.Bauer, M.S., McBride, L., Williford, W.O., Glick, H., Kinosian, B., Altshuler, L., et al. (2006). Collaborative care for bipolar disorder: Part II. Impact on clinical outcome, function, and costs. Psychiatric Services, 57, 927-936. Reason for exclusion: Self-management is viewed as part of a larger intervention package.
4. Fagiolini, A., Frank, E., Axelson, D.A., Birmaher, B., Cheng, Y., Curet, D.E. et al., (2009). Enhancing outcomes in patients with bipolar disorder: results from the bipolar disorder centre for Pennsylvanians study. *Bipolar Disorders*, 11, 382-390. Reason for exclusion: Prodromal monitoring is not a focus of the research study.
5. Jones, S.H. and Burrell-Hodgson (2008). Cognitive-behavioural treatment of first diagnosis bipolar disorder. *Clinical Psychology and Psychotherapy*, 15, 367-377. Reason for exclusion: The study did not use a RCT design.
6. Lam, D. and Wong, G. (2005). Prodromes, coping strategies and psychological interventions in bipolar disorders. *Clinical Psychology Review*, 25, 1028-1042. Reason for exclusion: The paper provides a review of prodromal monitoring.
7. Lam, D., Wong, G. and Sham, P. (2001). Prodromes, coping strategies and course of illness in bipolar affective disorder- a naturalistic study. *Psychological Medicine*, 31 (8), 1397-1402. Reason for exclusion: The study did not use a RCT design.

8. Micklowitz, D.J., Otto, M.W., Frank, E., Reilly-Harrington, N.A., Wisniewski, S.R., Kogan, J.N. (2007). Psychosocial treatments for bipolar depression: A 1-year randomized trial from the systematic treatment enhancement program. *Archives of General Psychiatry*, 64, 419-427.
Reason for exclusion:
An intervention approach (daily mood charting) that is used within a prodromal monitoring approach was used in both the control and experimental groups.

9. Miklowitz, D.J., George, E.L., Richards, J.A., Simoneau, T.L., and Suddath, R.L. (2003). A randomised study of family-focused psychoeducation and pharmacotherapy in the outpatient management of bipolar disorder. *Archives of General Psychiatry*, 60, 904-912.
Reason for exclusion:
Relapse prevention was used as an intervention in both the control and experimental groups.

10. Morriss, R. (2004). The early warning symptom intervention for patients with bipolar affective disorder. *Advances in Psychiatric Treatment*, 10, 18-26.
Reason for exclusion:
Paper provides an overview of prodromal monitoring work.

11. Novacek, J. and Raskin, R. (1998). Recognition of early warning signs: A consideration for cost-effective treatment of severe mental illness. *Psychiatric Services*, 49, 376-378.
Reason for exclusion:
Sample included individuals with a diagnosis of schizophrenia, bipolar disorder, and unipolar depression. Separate data was not provided for each type of disorder.

12. Palmer, A.G., Williams, H. and Adams, M. (1995). CBT in a group format for bi-polar affective disorder. *Behavioural and Cognitive Psychotherapy*, 23, 153-168.
Reason for exclusion:
The study did not use a RCT design.

13. Pollack, L. (1996). Inpatient self-management of bipolar disorder. *Applied Nursing Research*, 9(2), 71-79.
Reason for exclusion:
Qualitative research approach used.

14. Russell, S.J. (2008). Role of a 'stay well' approach in the management of bipolar disorder. *Australian and New Zealand Journal of Psychiatry,* 42 (7), 551-554.
Reason for exclusion:
Ethos of the staying well approach is described in the paper but no outcome data is reported.

15. Russell, S.J. and Browne, J.L. (2005). Staying well with bipolar disorder. *Australian and New Zealand Journal of Psychiatry*, 39, 187-193.
Reason for exclusion:
Study used a qualitative approach.

16. Scott, J., Paykel, E., Morriss, R., Bentall, R., Kinderman, P., Johnson, T. et al. (2006). Cognitive-behavioural therapy for severe and recurrent bipolar disorders. *British Journal of Psychiatry*, 188, 313-320.
Reason for exclusion:
The role of prodromal monitoring in the intervention group was unclear.

17. Simoneau, T.L., Miklowitz, D.J., Richards, J.A., Saleem, R., and George, E.L. (1999). Bipolar disorder and family communication: Effects of a psychoeducational treatment program. *Journal of Abnormal Psychology*, 108 (4), 588-597.
Reason for exclusion:
Prodromal monitoring was not viewed as key feature of the intervention.

18. Stevens, S. (2005). Implementing a self-management model of relapse prevention for psychosis into routine clinical practice. *Journal of Psychiatric and Mental Health Nursing*, 12,495-501.
Reason for exclusion:
Sample includes individuals with psychosis, therefore not exclusively looking at individuals with bipolar disorder.

19. Wright, J. and Austin, Z. (1996). An individualized self-monitoring instrument (ISMI) to promote self-management in bipolar illness. The Canadian Journal of Hospital Pharmacy, 49 (3), 164-166.
Reason for exclusion:
Case study approach used.

20. Zaretsky, A.. Segal, E., Z. V., and M. Gemar. (1999). Cognitive therapy for bipolar depression: A pilot study. *Canadian Journal of Psychiatry,* 44, 491-494.
Reason for exclusion:
Role of prodromal monitoring in the intervention is unclear.

Appendix 3: Methodological rating form

Note: If not enough information is given regarding a specific item a rating of 0 is given.

1. Clarity of sample description

0 Poor. Vague description of sample (e.g. only mentioned whether patients were diagnosed with the disorder).

1 Fair. Fair description of sample) (e.g. mentioned inclusion/exclusion criteria, demographics etc).

2 Good. Good description of sample (e.g. mentioned inclusion/exclusion criteria, demographics, prevalence of co-morbid disorders, information on illness history such as length, time since diagnosis).

2. Representativeness of the sample

0 Poor. Sample is very different from the patients seeking treatment for the disorder (e.g. there is unfair exclusion criteria).

1 Fair. Sample is somewhat representative of patients seeking treatment for the disorder (e.g. patients were only excluded if they met criteria for other major disorders).

2 Good. Sample is very representative of patients seeking treatment for disorder (e.g. authors made efforts to ensure representatives of the sample).

3. Reliability of diagnosis in question

0 Poor. The diagnostic process was not reported, or not assessed with structured interviews by a trained interviewer.

1 Fair. The diagnosis was assessed with structured interview by a trained interviewer.

2 Good. The diagnosis was assessed with structured interview by a trained interviewer and adequate inter-rater reliability was demonstrated (e.g. kappa coefficient

4. Specificity of outcome measures

0 Poor. Very broad outcome measures, not specific to the disorder (e.g. SCL-90R total score).

1 Fair. Moderately specific outcome measures

2 Good. Specific outcome measures, such as a measure for each symptom cluster.

5. Reliability and validity of outcome measure

0 Poor. Measures have unknown psychometric properties, or properties that fail to meet current standards of acceptability.

1 Fair. Some, but not all measures have known or adequate psychometric properties.

2 Good. Al measures have good psychometric properties. The outcome measures are the best available for the author's purpose.

6. Use of blind evaluators

0 Poor. Blind assessor was not used

1 Fair. Blind assessor was used but no checks were used to assess the blind.

2 Good. Blind assessor was used in the correct fashion. Checks were used to assess whether the assessor was aware of the treatment condition.

7. Assessor training

0 Poor. Assessor training or accuracy are not specified, or are unacceptable.

1 Fair. Minimum criterion for assessor training is specified (e.g. Assessor has had specific training in the use of the outcome measure), but accuracy not monitored or reported.

2 Good. Minimum training of assessor training is specified. Inter-rater reliability was checked, and/or assessment procedures were calibrated during the study to prevent evaluator drift.

8. Assignment to treatment

0 Poor. Biased assignment, e.g. patients selected their own

1 Fair. Random or stratified assignment. There may be some systematic bias but not enough to pose a serious threat to internal validity. There may be therapist by treatment confounds. N may be to small to protect against bias.

2 Good. Random or stratified assignment, and patients are randomly assigned to therapies within condition. When theoretically different treatments are used, each treatment is provided by a large enough number of different therapists. N is large enough to protect against bias.

9. Design

0 Poor. Active treatment vs. WLC, or briefly described TAU.

1 Fair. Active treatment vs. TAU with good description or placebo condition.

2 Good. Active treatment vs. another previously empirically documented active treatment.

10. Power analysis

0 Poor. No power analysis was made *a priori* to the initiation of the study.

1 Fair. No power analysis based on an estimated effect size was used.

2 Good. A data-informed power analysis was made and the sample size was decided accordingly.

11. Assessment points

0 Poor. Only pre and post-treatment follow-up or pre and follow-up.

1 Fair. Pre, post and follow-up < 1 year.

2 Good. Pre, post and follow-up > 1 year.

12. Manualised replicable, specific treatment programme

0 Poor. Description of treatment procedure is unclear, and treatment is not based on publicly available, detailed treatment manual.

1 Fair. Treatment is not designed for the disorder or description of the treatment is clear and based on a publicly available and detailed manual. However, there are some ambiguities about the procedure. Patients may have received additional forms of treatment but this is balanced between-groups or otherwise controlled.

2 Good. Treatment is designed for the disorder. A detailed manual is available, and/or treatment is explained in sufficient detail for replication. No ambiguities about the treatment procedure. Patients only receive the treatment under investigation.

13. Number of therapists

0 Poor. Only one therapist, i.e. complete confounding between therapy and therapist.

1 Fair. At least two therapists, but the effect of therapist on outcome is not analysed.

2 Good. Three or more therapists and the effect of therapist on outcome is analysed.

14. Therapist training/experience

0 Poor. Very limited clinical experience of the treatment/disorder (e.g. students).

1 Fair. Some clinical experience of the treatment/disorder.

2 Good. Long clinical experience of the treatment/disorder (e.g. practising therapists).

15. Checks for treatment adherence

0 Poor. No checks were made to assure that the intervention was consistent with protocol.

1 Fair. Some checks were made (e.g. assessed a proportion of therapy tapes).

2 Good. Frequent checks were made (e.g. weekly supervision of each session using a detailed rating form).

16. Checks for therapist competence

0 Poor. No checks were made to assure that the intervention was delivered appropriately.

1 Fair. Some checks were made (e.g. assessed a proportion of therapy tapes).

2 Good. Frequent checks were made (e.g. weekly supervision of each session using a detailed rating form).

17. Medication adherence measured and controlled for in statistical analysis if required

0 Poor. No attempt to measure and control for medication adherence.

1 Fair. Medication adherence measured but between-group differences not explored or information not used as a covariate in subsequent statistical analyses.

2 Good. Medication adherence measured and information used to investigate between-group differences and when required used as a covariate in relevant statistical analyses.

18. Control for concomitant psychological treatments

0 Poor. No attempt to control for concomitant psychological treatments.

1 Fair. Asked participants not to take part in other psychological treatments during and post study period.

2 Good. Ensured that participants did not receive any other psychological interventions.

19. Handling of attrition

0 Poor. Proportions of attrition are not described or described but no dropout analysis is performed.

1 Fair. Proportions of attrition are described and dropout analysis or intent-to-treat analysis is performed.

2 Good. Attrition or the proportion of attrition is described, dropout analysis is performed and results are presented as intent-to-treat analysis.

20. Statistical analysis and presentation of results

0 Poor. Inadequate statistical methods are used and/or data is not fully presented.

1 Fair. Adequate statistical methods are used but data are not fully presented.

2 Good. Adequate statistical methods are used and data is fully presented

21. Equality of therapy hours (for non-WLC designs only)

0 Poor. Conditions differ markedly (> 20 percent difference in therapy hours).

1 Fair. Conditions differ somewhat (10-19 percent difference in therapy hours).

2 Good. Conditions do not differ (<10 percent difference in therapy hours).

Appendix 4. Data extraction form

Study name:	**county of origin:**
Aims	
Methods	
recruitment: allocation: blinding: research setting: duration of study: period: inclusion criteria: exclusion criteria:	follow-up
Participants	
diagnosis: matched on demographic variables at baseline: matched on illness-related factors (e.g. no. of episodes) at baseline: Control group Experimental group age: female: sample size: attrition rate**:**	
Intervention description	
Control group: Content of group intervention:	
Measures	
Outcomes	
Overview of analysis: Definition of relapse: Results:	
Additional information	
Are the tests appropriate for the data used: Are confounding variables adequately controlled: Is the research ethical? Is the design ecologically valid? Medication adherence controlled? Sample size: Treatment fidelity measured: Methodological quality:	

Appendix 5: Key study details

Key methodological, design features, and research outcomes of the reviewed research studies

Study	Country	Aims	Participant information	Co-morbidit used as exclusion criteria
Castle *et al.* (2007)	Australia	To assess whether a group intervention reduced the rate of relapse and improved the quality of life for people with Bipolar Disorder.	Experimental Control Sample size: 9 8 Females: 7 7 Age: 44(± 13) 44(± 8) Diagnosis: Bipolar 1 & II	X
Colom *et al.* (2003a)	Spain	To compare the efficacy of group psychoeducation with standard treatment for reducing rate of relapse for people with Bipolar Disorder.	Experimental Control Sample size: 60 60 Females: 38 38 Age of onset: 22.26 (±6.29) 23.25 (±7.55) Diagnosis: Bipolar I & II	√
Colom *et al.* (2003b)	Spain	To assess the efficacy of psychoeducation, with reference to reduction in episodes with a optimal treatment adherence group of participants.	Experimental Control Sample size: 25 25 Females: 15 16 Age: 35.36(±10.87) 34.48 (±10.87) Diagnosis: Bipolar 1	√
Colom *et al.* (2009a)	Spain	To assess the long-term efficacy of group psychoeducation designed to reduce recurrences of episodes and time spent in an episode for people with Bipolar Disorder.	Experimental Control Sample size: 60 60 Females: 38 38 Age: 34.03(±9.32) 34.26 (±7.80) Diagnosis: Bipolar I & II	√
Colom *et al.* (2009b)	Spain	To carry out a post-hoc analysis with Bipolar II patients involving data designed to assess the effectiveness of a psychoeducation group which was designed to reduce relapse rates.	Experimental Control Sample size: 8 12 Females: ? ? Age: 40 40 Diagnosis: Bipolar II	√

Lam *et al.* (2000)	United Kingdom	To assess the effectiveness of a time-limited relapse prevention package designed to increase mood stability and reduce relapse rate for people with Bipolar Disorder.	Experimental Control Sample size: 13 12 Females: ? ? Age: 39 (±10.9) Diagnosis: Bipolar Disorder I	√
Lam *et al.* (2003)	United Kingdom	To assess the effectiveness of a Cognitive Therapy for reducing relapses and promoting social functioning for patients with Bipolar Disorder.	Experimental Control Sample size: 52 51 Females: 30 28 Age: 41.5(±10.8) 46.4 (±12.1) Diagnosis: Bipolar I	√
Lam *et al.* (2005)	United Kingdom	To investigate the long-term effect of Cognitive Therapy (2-year follow-up) for patients with Bipolar Disorder.	Experimental Control Sample size: 52 51 Females: 30 28 Age: 41.5 (±10.8) 46.4(±12.1) Diagnosis: Bipolar I	√
Perry *et al.* (1999)	United Kingdom	To determine if prodromal monitoring of manic and depressive symptoms reduces rates of relapse for bipolar patients.	Experimental Control Sample size: 34 35 Females: 23 4 Age: ? ? Diagnosis: Bipolar I & II	X
Scott *et al.* (2001)	United Kingdom	To explore the feasibility and potential benefits of Cognitive Therapy for reducing relapse rates, hospital admissions and improve quality of life for people with Bipolar Disorder.	Experimental Control Sample size: 21 21 Females: 11 11 Age: 40.5(±6.7) 37.8(±8.7) Diagnosis: Bipolar Disorder I and II	X
Simon *et al.* (2004)	USA	To evaluate a multi-component care management programme for people with Bipolar Disorder.	Experimental Control Sample size: 212 229 Females: 144 157 Age at onset: 44.1(±13.4) 44.3 (±12.9) Diagnosis: Bipolar Disorder I& II	X

Study	Intervention/control	Test/ Follow-up period	Measures	Summary of results
Castle *et al.* (2007)	*Experimental group*: Group intervention psychoeducation. Ninety min sessions run by two research assistants included prodromal monitoring, coping skills and psychoeducation *Control group*: TAU (pharmacological treatments and continued care via GP/Psychiatrist	12 weeks/ 3 months	MINI, MADRS, YMRS, GAF, WHOQoLBREF, MARS	Definition of relapse: **if participants met the IV criteria for a manic or depressive e and/or required hospital admission.** i. Social functioning significantly improved intervention group. ii. Social relationship subscale of the WHOQol showed significant improvement for inter group. iii. 1 person in intervention group experienced compared to 4 in the control group (non-sig result.
Colom *et al.* (2003a)	*Experimental group*: Manualised psychoeducation delivered in a group format. Twenty-one sessions of 90 minutes consisting of: illness awareness, treatment compliance, early detection of prodromal symptoms and recurrences, and life style regularity. Conducted by experienced clinical psychologists + TAU *Control group:* 21 weeks of treatment as usual (TAU) i.e. standard psychiatric care and pharmacological treatment, group meetings 8-12 participants (without specific instruction from psychologist).	20 weeks/ 2 years	SCID I & II, RS, HDRS-17, Holmes and Rahe inventory for stressful life events. Medication compliance measured via interviews with participant and significant other and plasma concentrations of mood stabilisers.	Definition of relapse: **participant fulfilling D criteria or clinical cut-offs on the YMRS HDRS)** i. During intervention and at 2-year fol significantly more participants in the contro relapsed. ii. Time to reoccurrence was significantly sh the control group for manic, depressive and episodes. iii. At follow-up significantly more patients in group had relapse for depressive episod compared with the experimental group t manic/Hypomanic episodes. iv. More patients in the control group hospitalised during treatment (non-sign result) this result was significant at follow-up v. No difference was observed between t hospitalisation for the two groups but pe

				control group spent significantly more t hospital.
Colom *et al.* (2003b)	As above	20 weeks/ 2 years	As above	Definition of relapse: A score of 12+ on the or the HAM-D. Once relapse confirmed the D criteria was applied to determine polarity episode. i. Significantly more patients in the control fulfilled criteria relapsed during the treatm follow-up stage compared to the treatment gr ii. Participants who relapsed in experimental had significantly longer period between episo iii. The number of total recurrences was signif lower in the treatment group. iv. Significantly fewer participants in the tre group experienced a manic, mixed, or dep episode in the follow-up stage when compar the control group. v. Significantly more patients in the control were hospitalised (N = 4) compared to pati the treatment group (N=0). vi. Significantly more patients in the control (N=9) were hospitalised at the follow-up compared with 2 from the treatment group.
Colom *et al.* (2009a)	As described in Colom *et al.* (2003a) *Follow-up period:* 5 year period, during this time all participants continued to receive standard pharmacological treatment without psychological intervention in the study centre.	20 weeks/ 5 years	As above	Definition of relapse/recurrence: **Defined emergence of a new acute episode accord DSM-IV criteria and scores above or equa on the YMRS and 12 on the HDRS-17 for recurrence.** i. The psychoeducation group had significantly recurrences and longer time between ep When type of episode was reviewed a s lower effect size was observed for dep episodes ii. People in the psychoeducation group

				significantly fewer days ill: this was signific all types of episodes. iii. Significantly fewer people in the psychoed group were hospitalised. The median nun days spent in hospital was significantly lo the psychoeducation group. iv. At five year follow-up there was no sigr between group differences in medi adherence. There was a reduction in rates adherence for both groups from entry to follow-up.
Colom *et al.* (2009b)	As described in Colom *et al.* (2003a)	20 weeks/ 5 years	As above	Definition of relapse/recurrence: **Defined emergence of a new acute episode according to IV criteria and scores above or equal to 20 YMRS and 12 on the HDRS-17 for mixed recur** i. No between group differences in reoccurren (i.e. as defined by DSM-IV or indicated by and/or HDRS) were observed during inter stage. ii. At five year follow-up there was a sigr difference in rates of relapse with more pe control group (100%) relapsing. iii. Significantly more participants in the contro experienced a Hypomanic episode. iv. Significantly more participants in the contro experienced a depressive episode and a Hyp episode. v. There was no significant difference regard number of patients who required hospitalisa the mean number of days spent in hospita group differences were explored.
Lam *et al.* (2000)	*Experimental group:* One to one CBT sessions. Patients seen for an average of 15 sessions which included: teaching of CBT skills to cope with prodromes, identifying early warning signs & implementing coping strategies, introduction of the	6 months/ 12 months	MAS, ISS, BHS, MRC, SPS, SCBS, Early Warning and Coping Interview, MCQ, MHVT.	Definition of relapse: **any major bipolar e that fulfilled DSM-IV criteria for depression, mania, or hypomania.** i. When data was adjusted for gender, pr episodes, previous number of hospitalis suicide attempts a significant effect for hyp

	stress diathesis model, psychoeducation (e.g. importance of sleep and routine, dealing with long term vulnerabilities associated with illness). Four clinical psychologists with a minimum of 6 years post qualification experience delivered the treatment. *Control group:* TAU (routine outpatient care and appropriate MDT input as required) The research team had no influence over MDT input.		SADS.	suicide attempts a significant effect for hyp and total bipolar episodes was found was between the 2 groups. ii. The experimental group were significantly b coping with manic prodromes at 6 and 12 and significantly better at coping with dep prodromes at 12 months. iii. The experimental group had significantly MAS score at 12 months. The experimenta had significantly lower BHS at 6 months bu 12-month follow-up. iv. Significant difference on the SPS score v improvement in the experimental grou experimental group had significant impro on the SCBS at 6 and 12 months. v. Experimental group had significantly lowe scores over the 12-month period. vi. Experimental group had significantly medication compliance.
Lam *et al.* (2003)	*Experimental group:* Cognitive Therapy manualised approach (CT) <u>one to one sessions</u> CT (information on diathesis-stress model; CBT for mood monitoring, prodromal monitoring, behaviour modification to manage prodromes, psychoeducation on importance of sleep and routine, work on extreme striving attitudes) lasted for 12-18 sessions within a 6-month period. Two booster sessions in second 6 months administered by four Clinical Psychologists (3 male, experience 5 yrs +) + TAU *Control group:* TAU	6 months/ 12 months	SCID-IV, MRCSPS, MHV (1995 Ed), Coping with Prodromes Interview, BDI, ISS, BHS, control subscale of DAS, MCQ.	Definition of relapse/recurrence: **Any major l episode that fulfilled DSM-IV criteria for depression, mania, or hypomania.** vii. Significantly fewer relapses in experimenta compared with control group. viii. The experimental group had significantly experiences of depressive, manic, hypo episodes in 12 month period. ix. The experimental group spent significantly days in hospital. x. The experimental group had significantly days in hospital for depressive not manic epis xi. A significant reduction in BDI scores, acros occurred in the experimental group. xii. There was significantly more mood fluctua the control group.

Lam *et al.* (2005)	*Experimental group:* Cognitive Therapy manualised approach one to one sessions. CT (same as above regarding therapy content) consisted of 12-18 individual sessions within 6 months and 2 booster sessions in second 6-months administered by four Clinical Psychologists (3 male, experience 5 yrs +). Participants were seen for an average of 14 sessions. *Control group:* TAU	6 months/ 30 months	CID, HDRS, BRMRS, Coping with Prodromes Schedule, SFS, (patients' description of coping with prodromes was transcribed verbatim), DAS, MCS	Definition of relapse/recurrence: **Any major l episode that fulfilled DSM-IV criteria for depression, mania, or hypomania.** i. Significant between group differences for first episode post intervention for depress not manic/Hypomanic episodes. Experi group experiencing bigger time delay. ii. At follow-up: iii. A non-significant difference in proport participants who had at least 1 relapse. iv. Significant between group differences for ı of days in a bipolar episode (previous episo medication compliance controlled for) experimental group experiencing shorter epis v. Significant between group difference for DA attainment at 18 months, social function months, coping with mania and depı prodromes at 24 months, mania ratings months in terms of the experimental group significantly better ratings compared to the group. vi. Based on self-report measures the experi group were more compliant at 24 and 30 co with the control group regarding their medica
Perry *et al.* (1999)	*Experimental group:* One to one therapy: 2-stage intervention was carried out by 1 research therapist: 1) patients were trained to identify manic and depressive prodromes. 2) An action plan was planned and rehearsed. Prodromal symptom information obtained via card sorting exercise and standard checklist. Diaries used to identify symptoms linked with normal mood variation. The patient identified three health care professionals to approach for early treatment (one of whom would be available at all times). Relapse plan was printed on a laminated card the patient carried + TAU. *Control group:* TAU	12 weeks/ 15 months	SCID II	Definition of relapse/recurrence: **A minimuı days of symptoms of mania, hypomania, affective disorder, or major depression acc to standardised symptom criteria**. i. Time to first manic relapse was significantly in th control group. ii. There was no significant difference in leı manic episode between the two groups. iii. 18 months post study there was a sigr difference in overall social functionin employment in the experimental group.

Scott *et al.* (2001)	*Experimental group:* One to one Cognitive Therapy sessions Participants received up to 25 sessions. Therapy included an approach for symptom management (self-monitoring), relapse prevention techniques which included prodromal monitoring and coping strategies for identified early warning symptoms. Two therapists with experience in working with severe affective disorders delivered the therapy.+ TAU Control group: WLC (TAU)	6 months/ 18 months	SADS-L and the GAF, PDQ-R, WASA, ISS, BDI, SCL-90.	Definition of relapse/recurrence: **When partic meet diagnostic criteria for an affective episo** i. Experimental group showed a significant re in the following mood measures: BDI, IS ACT, PC and GAF. A non-sign improvement was noted in the ISS_WB, CL WASA data. ii. When WASA subscale analysis was c significant improvement in the CT group fo social activities involving others. iii. A greater reduction in symptoms tha diagnostic criteria for affective episode obse the experimental group but effect not signific iv. A significant reduction in symptom improvement in functioning found imme following CT compared with pre-CT ratii following measures: GAF, WASA, BDI, IS ISS ACT, Scl-90). v. A significant improvement also found pre (at follow-up 18 months, however an incr symptoms was observed. vi. A significant change in mental state over tir observed with fewer people meeting crite relapse or persistent illness after CT. vii. Hospital admission rates were also lower p post treatment: 1 year pre CT: 38%, duri 0%, and 1 year post CT: 7%. \
Simon *et al.* (2004)	Experimental group: One to one assessment and group intervention Received initial assessment (which included typical early signs of mood episodes and coping strategies) and care planning structured monthly telephone monitoring of mood symptoms and medication use, feedback to mental health team, additional support when required (e.g. crisis intervention) and a structured	Unclear/ 20 months	SCID, ISS, PSR score based on information from SCID.	**Definition of relapse/recurrence:** Defined clinical cut-offs on the SCID Psychiatric Rating scale i. The treatment group had significantly lower over 12 month period for mania symptoms. ii. There was a significant between group eff time spent in hospital (manic episode) with individuals in the experimental group havin

	psychoeducation group. Care managers (nurse care managers with minimum 5 years clinical experience) administered the treatment. Group consisted of 5 weekly sessions followed by twice monthly sessions for duration of intervention. Stage 1 included early symptom monitoring and coping strategies, education about bipolar disorder, and triggers. Stage 2 focused on life goals. Information on self-management plans (e.g. early symptom monitoring) were also updated in stage 2.			time in hospital. iii. No significant between group difference wa for depressive scores throughout the fol period. iv. A significant group x time interaction was f depressive symptoms in the experimental showed larger decline over time. v. No significant between group differen medication adherence (it is however unclear whether medication adherence was monitored

Appendix 6: In-depth study details for relevant research

(BDI = bipolar I disorder, BDII = bipolar II disorder).

1. Study name: Castle *et al.* (2007) **county of origin:** Australia

Aims

A pilot study designed to assess the effectiveness of a collaborative therapy package for people with BD. A key aim was to assess whether the package reduced rates of relapse, improved global functioning, and quality of life for people with BD.

Methods

recruitment: participants were referred by service providers at public and private treatment facilities, self-referral, and nongovernmental organisations.
allocation: random
blinding: √
research setting: outpatient clinic
duration of study: 12 weeks **follow-up period**: 3 months
inclusion criteria: current DSM-IV diagnosis of BD, 18 years old and over, able to converse in English, under the care of a medical practitioner, no evidence of organic aetiology or developmental disability.
exclusion criteria: if symptom severity would interfere with ability to take part in group programme

Participants

diagnosis: BD I, BD II
matched on demographic variables at baseline: √
matched on illness-related factors (e.g. no. of episodes) at baseline: √

	Control group	Experimental group
age:	44 (±8)	44 (±13)
female:	7	7
sample size:	9	8
attrition rate:	0	0

information on marital status provided

Intervention description

Control group: TAU (i.e. pharmacological treatment and continued care by GP or psychiatrist) + weekly phone calls to control for extra contact time with researchers
Experimental group: TAU + group-based intervention
Content of group intervention: group intervention delivered in an out-group setting once a week for 90 minutes over a period of 12 weeks. Group content: education, peer support, new coping strategies, managing and monitoring prodromes and cognitive skills. Participants encouraged to record information in participant work book. Phone calls made between sessions to offer support for homework tasks. Manualised approach used to ensure treatment fidelity. The groups were run by 2 research assistants with clinical experience and training of psychosocial group interventions and group activities.

Measures

Participants assessed at baseline and at 6 months regarding: psychiatric status, relapse rates, social functioning, quality of life, and level of functioning.
Measures used: MINI, MADRS, YMRS, GAF, WHOQoLBREF, MARS.

Outcomes
Overview of analysis: ANCOVA and Ordinal Logistic Regression Analysis used (dependent variable was outcome measure at 6 months, measure and baseline, independent variable was group type). Chi-square, Mann-Whitney U Test, and T-Tests used to analyse baseline characteristics (depending on data type). **Definition of relapse:** If participants met the DSM-IV criteria for a manic or depressive episode, and/or required hospital admission. **Results:** Four control participants experienced relapse compared with one relapse in experimental group (non-significant result). Social functioning was found to significantly improve in the intervention group. Social relationship subscale on the WHOQoLBREF showed significant results for intervention group
Additional information
Are the tests appropriate for the data used: X some of the tests are inappropriate for sample size of 17 participants (i.e. Ordinal Regression Analysis with 10 predictor variables) Are confounding variables adequately controlled: √ Is the research ethical? √ Is the design ecologically valid? √ Medication adherence controlled? X Sample size: small Treatment fidelity measured: X Methodological quality: moderate

2. Study name: Colom, *et al.* (2003a) **county of origin:** Spain

Aims

To compare the efficacy of group psychoeducation with standard treatment

Methods

recruitment: participants were recruited from individuals enrolled in the naturalistic follow-up of the Bipolar Disorders Program of the Hospital Clinic (University of Barcelona)
allocation: randomised
blinding: √
research setting: clinical setting
duration of study: 20 weeks **follow-up period**: 2 year
inclusion criteria: life time diagnosis of BD I or II, euthymic for at least 6 months, ability to provide consent, and sufficient data available for prior course of illness.
exclusion criteria: DSM-IV Axis 1 co-morbidity (not including caffeine and nicotine dependence), IQ <70, organic brain damage, deafness, in current receipt of psychotherapy or participating in a pharmacological trial.

Participants

diagnosis: BDI, BD II
matched on demographic variables at baseline: √
matched on illness-related factors (e.g. no. of episodes) at baseline: √

	Control group	Experimental group
Age at onset:	23.25 (7.55)	22.26 (6.69)
female:	38	38
sample size:	60	60
attrition rate:	7	16

no information on relationship status or employment status.

Intervention description

Control group: 21 weeks of treatment as usual (TAU) i.e. standard psychiatric care and pharmacological treatment, group meetings 8-12 participants (without specific instruction from psychologist)
Experimental group: TAU + manualised psychoeducation delivered in a group format (21 sessions of 90 minutes) consisting of: illness awareness, treatment compliance, early detection of prodromal symptoms and recurrences, and life style regularity. Conducted by experienced clinical psychologists.

Measures

Baseline: SCID I and II, YMRS, HDRS-17, Holmes and Rahe inventory for stressful life events. Medication compliance measured via interviews with participant and significant other and plasma concentrations of mood stabilisers.

Outcomes

Overview of analysis:
Recurrence-Free Curve analysis using Kaplan-Meir survival analysis used. To explore between-group baseline characteristics chi-square tests, t-test and fisher exact probability test was used (depended on data type).

Definition of relapse:
Participant fulfilling DSM-IV criteria or clinical cut-offs on the YMRS and/or HDRS)

Results:
During intervention and at 2 year follow-up significantly more participants in the control group relapsed.
Time to reoccurrence was significantly shorter in the control group for manic, depressive and mixed episodes.
At follow-up significantly more patients in control group had relapse for depressive episode when compared with the experimental group.
At follow-up more patients in control group had manic and/or Hypomanic relapse (non-significant result).
More patients in the control group were hospitalised during treatment (non-significant result)
At 12 month follow-up control group had significantly more hospital admissions significant result.
The mean number of days in hospital was significantly higher for the control group.
No difference was observed between time to hospitalisation for the two groups.
At two year follow-up a significant difference was observed between the two groups regarding Lithium levels but not valporate levels.

Additional information

Are the tests appropriate for the data used: √
Are confounding variables adequately controlled: √
Is the research ethical? √
Is the design ecologically valid? X Participants not recruited from clinical setting
Medication adherence controlled for in analysis? √
Sample size: moderate
Treatment fidelity measured: √
Methodological quality: moderate

3. Study name: Colom *et al.* (2003b) **county of origin:** Spain

Aims

To assess the efficacy of psychoeducation in euthymic patients with optimal treatment adherence.

Methods

recruitment: Patients recruited from a sample of 400 patients enrolled in the naturalistic prospective follow-up of the Bipolar Disorders Program at the University of Barcelona.
allocation:
blinding: √
research setting: clinical setting
duration of study: 20 weeks **follow-up period**: 2 years
inclusion criteria: DSM-IV criteria for Bipolar Disorder I, aged 18-65 years old, being euthymic, score of <6 on the HAM-D, (<8 for minimum of 6 months), sufficient information on prior course of illness, good treatment compliance demonstrated by three compliance assessments (patient and significant other compliance interview and plasma concentrations of mood stabliser).
exclusion criteria: DSM-IV co-morbidity (except for caffeine and nicotine dependence), IQ < 70, organic brain damage, involvement in other forms of therapy during trial period.

Participants

diagnosis: BDI
matched on demographic variables at baseline: √
matched on illness-related factors (e.g. no. of episodes) at baseline: √

	Control group	Experimental group
Age at onset:	23.12 (7.36)	22.96 (7.05)
Age:	34.48 (7.80)	35.36 (10.87)
female:	16	15
sample size:	25	25
attrition rate:	0	0

no information on marital or employment status.

Intervention description

Control group: 20 weeks of TAU (i.e. standard psychiatric care and pharmacological treatment, group meetings 8-12 participants (without specific instruction from psychologist)
Experimental group: TAU + manualised psychoeducation delivered in a group format (20 sessions of 90 minutes) consisting of: illness awareness, treatment compliance, early detection of prodromal symptoms and recurrences, and life style regularity. Conducted by two experienced psychologists.

Measures

Baseline assessment (carried out by psychiatrist) involved: SCID-I and SID-II, YMRS, HAM-D, Holmes and Rahe inventory for stressful life events. Information noted on medication and reasons for change in medication. Assessed monthly by psychiatrist and weekly by a research assistant for: information on number of hospitalisations, reasons for admission, total days spent in hospital, symptom checking, treatment registration. Medication compliance assessed via compliance interview with patient, family member and plasma concentrations of mood stablisers.

Outcomes
Overview of analysis: Chi-square (or Fisher Exact Probability when required) used to examine dichotomous demographic factors, relapse during follow-up. T-test was used to examine data regarding relapse during treatment and follow-up. Recurrence curve analyses by Kaplan-Meyer's survival analysis. ANOVAs used to test the impact of CBT/PE on social scores and relapse rates. Analysis was on an intention-to-treat analysis. **Definition of relapse:** A score of 12+ on the YMRS or the HAM-D. Once relapse confirmed the DSM-IV criteria was applied to determine polarity of the episode. **Results:** Recurrences Significantly more patients in the control group fulfilled criteria for recurrence during the treatment and follow-up phase compared to the treatment group. When relapse patients reviewed significant difference time to relapse (which showed longer time for treatment group). The number of total recurrences were significantly lower in the treatment group. Significantly fewer participants in the treatment group experienced a manic or mixed episode in the treatment stage when compared with the control group. Significantly fewer participants in the treatment group experienced a manic, mixed, or depressive episode in the follow-up stage when compared with the control group. Significantly more patients in the control group were hospitalised (N = 4) compared to patients in the treatment group (N=0). Significantly more patients in the control group (N=9) were hospitalised at the follow-up stage compared with 2 from the treatment group.
Additional information
Are the tests appropriate for the data used: √ Are confounding variables adequately controlled: X no controlling but no significant differences at baseline. Is the research ethical? √ Is the design ecologically valid? √ Medication adherence controlled for in analysis: X no but no between-group differences at baseline or follow-up. Sample size: moderate Treatment fidelity measured: X Methodological quality: moderate

4. Study name: Colom *et al.* (2009a) **county of origin:** Spain

Aims

To assess the long-term efficacy (5 years) of group psychoeducation designed to prevent recurrences and to reduce time spent ill for people with Bipolar Disorder.

Methods

recruitment: participants were recruited from individuals enrolled in the naturalistic follow-up of the Bipolar Disorders Program of the Hospital Clinic (University of Barcelona)
allocation: randomised
blinding: √
research setting: clinical setting
duration of study: 20 weeks **follow-up period**: 5 years
inclusion criteria: life time diagnosis of BD I or II, euthymic for at least 6 months, ability to provide consent, and sufficient data available for prior course of illness.
exclusion criteria: DSM-IV Axis 1 co-morbidity (not including caffeine and nicotine dependence), IQ <70, organic brain damage, deafness, in current receipt of psychotherapy or participating in a pharmacological trial.

Participants

diagnosis: BDI, BD II
matched on demographic variables at baseline: √
matched on illness-related factors (e.g. no. of episodes) at baseline: √

	Control group	**Experimental group**
Age:	34.26 (7.80)	34.03 (9.32)
Age at onset:	23.25 (7.55)	22.26 (6.69)
female:	38	38
sample size:	60	60
attrition rate:	7	16
attrition rate:	11	10 at follow-up

no information on marital or employment status

Intervention description

Control group: 21 weeks of TAU i.e. standard psychiatric care and pharmacological treatment, group meetings 8-12 participants (without specific instruction from psychologist)
Experimental group: TAU + manualised psychoeducation delivered in a group format (21 sessions of 90 minutes) consisting of: illness awareness, treatment compliance, early detection of prodromal symptoms and recurrences, and life style regularity. Conducted by experienced clinical psychologists.
Follow-up periods was 5 years: during this time all participants continued to receive standard pharmacological treatment without psychological intervention in the study centre.

Measures

Assessment of recurrences, symptom checking, and treatment registration was carried out every two months. The following measures were used: SCID-I, SCID-II, YMRS, HRSD-17, Holmes and Rahe inventory for stressful life events (also repeated if a new episode was suspected by the psychiatrist). Additional information that was recorded: reasons for medication change, number of hospitalisations, reasons for admission, total number of days in hospital. Medication adherence assessed through interview with participant, interview with significant other, analyses of plasma concentration of mood stabilisers.

Outcomes
Overview of analysis: Kaplan-Meyer's survival analysis used to examine recurrence. Cox proportional hazards regression analysis used to examine the association between number of previous episodes and time to recurrence (independent of other predictors). Covariates that were included in analyses: age at onset, number of previous episodes and number of hospitalisations. Analysis of baseline measures carried out by chi-square, fisher z-test, and t-tests dependent on data type. At follow-up chi-square used to examine number of patients who relapsed, ANCOVA used to examine comparison of mean number of recurrences during the treatment and the follow-up phase (covariates included age at onset, number of previous episodes, number of hospitalisations). **Definition of relapse/recurrence:** Defined as the emergence of a new acute episode according to DSM-IV criteria and scores above or equal to 20 on the YMRS and 12 on the HDRS-17 for mixed recurrence. **Results:** Significant between-group differences found for time to recurrence (shorter time for the control group). The psychoeducation group had significantly fewer recurrences. When type of episode was reviewed a slightly lower effect size was observed for depressive episodes (0.91 vs 0.80). People in the psychoeducation group spent significantly fewer days ill: this was significant for all types of episodes. Significantly fewer people in the psychoeducation group were hospitalised. The number of individuals hospitalised was lower in the psychoeducation group: this difference was not significant. The median number of days spent in hospital was significantly lower for the psychoeducation group. At five year follow-up there was no significant between-group differences in medication adherence. There was a reduction in rates of non-adherence for both groups from entry to 5-year follow-up.
Additional information
Are the tests appropriate for the data used: √ Are confounding variables adequately controlled: √ Is the research ethical? √ Is the design ecologically valid? √ Medication adherence controlled for in analysis: X (but no between-group differences) Sample size: good Treatment fidelity measured: √ Methodological quality: moderate

5. Study name: Colom, *et al.* (2009b) **county of origin:** Spain

Aims

To carry out a post-hoc analysis of data for BD II patients from a larger study (Colom *et al.* 2009a)

Methods

recruitment: participants were recruited from individuals enrolled in the naturalistic follow-up of the Bipolar Disorders Program of the Hospital Clinic (University of Barcelona)
allocation: randomised
blinding: √
research setting: clinical setting
duration of study: 20 weeks **follow-up period**: 5 year
inclusion criteria: life time diagnosis of BD I or II, euthymic for at least 6 months, and sufficient data available for prior course of illness., ability to provide consent
exclusion criteria: DSM-IV Axis 1 co-morbidity (not including caffeine and nicotine dependence), IQ <70, organic brain damage, deafness, in current receipt of psychotherapy or participating in a pharmacological trial.

Participants

diagnosis: BDII
matched on demographic variables at baseline: √
matched on illness-related factors (e.g. no. of episodes) at baseline: √

	Control group	Experimental group
Mean age:	40	40
female:	?	?
sample size:	12	8
attrition rate:	0	0 (sub-analysis from previous study)

limited demographic information. No information on marital or employment status.

Intervention description

Control group: 21 weeks of treatment as usual (TAU) i.e. standard psychiatric care and pharmacological treatment, group meetings 8-12 participants (without specific instruction from psychologist)
Experimental group: TAU + manualised psychoeducation delivered in a group format (21 sessions of 90 minutes) consisting of: illness awareness, treatment compliance, early detection of prodromal symptoms and recurrences, and life style regularity. Conducted by experienced clinical psychologists.

Measures

Baseline: SCID I and II, YMRS, HDRS-17, the SOFAS, and Holmes and Rahe inventory for stressful life events. Information on relapse rates, and hospitalisation recorded.

Outcomes

Overview of analysis:
The comparison of the baseline characteristics was carried out using Chi-Square, Mann Whitney U-Test and Fisher's Z dependent on the data type.

Definition of relapse/recurrence:
Defined as the emergence of a new acute episode according to DSM-IV criteria and scores above or equal to 20 on the YMRS and 12 on the HDRS-17 for mixed recurrence.

Results:
No between-group differences in reoccurrence rates were observed during intervention phase. At five year follow-up there was a significant difference in rates of relapse with more people in control group (100%) relapsing compared with intervention group (62.5%). Significantly more participants in the control group experienced a Hypomanic episode. Significantly more participants in the control group experienced a depressive episode (100%) compared with the intervention group (63%). The control group spent significantly more days with symptoms of hypomania and depression. There was no significant difference regarding the number of patients who required hospitalisation or the mean number of days spent in hospital. There were significant between-group differences on the SOFAS scores at 2- and 5-year follow-up; the scores indicated an improvement in the experimental group.

Additional information

Are the tests appropriate for the data used: √
Are confounding variables adequately controlled: √ BUT medication adherence not reported or included in analysis
Is the research ethical? √
Is the design ecologically valid? √
Medication adherence controlled for in analysis: X
Sample size: small
Treatment fidelity measured: X
Methodological quality: moderate

6. Study name: Lam *et al.* 2000 **county of origin:** United Kingdom

Aims

To assess the effectiveness of a time-limited relapse prevention package for Bipolar Disorder on mood stability and experience of frequent relapse.

Methods

recruitment: patients were approached to take part. Specific information not provided.
allocation: random
blinding: √
research setting: clinical setting
duration of study: 6 months **follow-up period**: 12 months
inclusion criteria: DSM-IV diagnosis of Bipolar Disorder, on prophylactic treatment, minimum of 2 episodes in the last two years or 3 in last 5 years, aged 18-65 years.
exclusion criteria: diagnosed with schizoaffective illness, currently in rapid cycling or mixed affective episode, currently in acute episode (BDI > 30, MRSS >9), involved in another form of psychotherapy, actively suicidal, with a primary alcohol or drug addiction.

Participants

diagnosis: BDI
matched on demographic variables at baseline: X
matched on illness-related factors (e.g. no. of episodes) at baseline: X matched on number of previous episodes but control group had significantly more hospitalisations and suicide attempts.

	Control group	Experimental group
sample size:	12	13
attrition rate:	1	1

demographic information given for two groups as a whole:
Mean age: 39 (10.9)
Female: 13
Information on marital and employment status provided.

Intervention description

Control group: TAU (routine outpatient care and appropriate MDT input as required) The research team had no influence over MDT input*.
Experimental group: TAU + CBT sessions (patients seen for an average of 15 sessions) which included: CBT skills to cope with prodromes, taught to identify early warning signs and implement coping strategies, psychoeducational model for Bipolar Disorder (i.e. stress diathesis model), importance of sleep and routine, dealing with long term vulnerabilities associated with illness. Patients were offered up to 20 sessions and clinical judgement was used to determine how many sessions to offer patients.
Four clinical psychologists with a minimum of 6 years post qualification experience delivered the treatment.

Measures

MAS, ISS, BHS, MRC, SPS, SCBS, Early Warning and Coping Interview, MCQ, MHVT. SADS used at recruitment, 6 and 12 months. Diagnosis of Bipolar episodes made by information from SAD and file review.

Outcomes
Over of analysis: Chi-square test used to analyse dichotomous data, Poisson regression for counts used to investigate number of episodes, ANOVA used for continuous variables and ANCOVA used when appropriate. **Definition of relapse/recurrence:** Definition of relapse: any major bipolar episode that fulfilled DSM-IV criteria for major depression, mania, or hypomania. **Results:** Episodes: Significantly more manic, hypomanic, depressed, total episodes and hospitalisation in the control group. When data was adjusted for gender, previous episodes, previous number of hospitalisations, suicide attempts a significant effect for hypomanic and total bipolar episodes was found. Mood measures (6 months and 12 months): The experimental group had lower mean scores at 6 and 12 months on the BDI, BHS, HRSD, MAS. The difference did not reach statistical significance. The experimental group had significantly lower MAS and scores at 12 months. The experimental group had significantly lower BHS at 6 months but not at 12 month follow-up. Significant differences on the SPS score with an improvement in the experimental group. The experimental group had significant improvement on the SCBS at 6 and 12 months. The experimental group were significantly better at coping with manic prodromes at 6 and 12 months. Also significantly better at coping with depressive prodromes at 12 months. Monthly measures of BDI, BHS, ISS, MCQ: Experimental group had significantly lower BHS scores over the 12-month period. Experimental group had significantly better medication compliance. However, experimental group had lower medication adherence and higher BHS scores at follow-up compared to scores at 6 months. Fluctuation in the experimental group scores on the BDI, BHS, MCQ and ISS found over the 12-month period. Medication: No significant difference in terms of no. of participants, in each group, being prescribed Lithium and carbamazepine, antidepressants at recruitment, 6 and 12 months. A significantly higher proportion of participants in the control group were on neuroleptics at 12 months. More participants in the control group were on 2+ types of mood stabilisers over the 12 month period.
Additional information
Are the tests appropriate for the data used: √ Are confounding variables adequately controlled: √ Is the research ethical? √ Is the design ecologically valid? Unclear how participants approached. Medication adherence controlled for in analysis: X Sample size: small Treatment fidelity measured: supervision provided and therapy sessions were audio-taped, however, no information provided on how taped sessions reviewed. Methodological quality: moderate

7. Study name: Lam *et al.* (2003) **county of origin:** UK

Aims

To assess the effectiveness of Cognitive Therapy compared to TAU as a means of preventing relapses and promoting social functioning.

Methods

recruitment: via psychiatrist referral or from maintenance clinic list
allocation: random
blinding: √
research setting: clinical setting
duration of study: 6 months **follow-up period**: 12 months
inclusion criteria: prescribed adequate dose of prophylactic medication; aged 18-70; at least 2 episodes in past 2 years or 3 in past 5 years; not fulfilling criteria for a episode.
exclusion criteria: actively suicidal (assessed by BDI suicide item score of 3); fulfilling criteria for substance use disorder

Participants

diagnosis: BDI according to DSM-IV
matched on demographic variables at baseline: √
matched on illness-related factors (e.g. no. of episodes) at baseline: √

	Control group	**Experimental group**
age:	M= 46.4 (±12.1)	41.5 (±10.8)
age of onset	26.2 (9.5)	28.2 (11.4)
female:	28	30
sample size:	51	52
attrition rate:	15.68%	15.68%

no information on marital status or employment status.

Intervention description

Control group: TAU
Experimental group: Cognitive Therapy manualised approach (CT) + TAU
CT consisted of 12-18 individual sessions within 6 months and 2 booster sessions in second 6 months administered by 4 Clinical Psychologists (3 male, experience 5 yrs +)
Content of CT: information on diathesis-stress model; CBT for mood monitoring, prodromal monitoring, behaviour modification to manage prodromes, psychoeducation on importance of sleep and routine, work on extreme striving attitudes.

Measures

SCID-IV, MRCSPS, MHV (1995 Ed), Coping with Prodromes Interview, BDI, ISS, BHS, control subscale of DAS, MCQ.
Collateral information: via interviews with key relative.

Outcomes
Overview of analysis: Group differences explored using the Chi-Square test for ordinal data and the Spearman Correlation Coefficient for skew data, ANOVA was used for continuous variables, and Cox Regression was used for survival analysis (number of weeks to first episode was the dependent variable). Logistic Regression was used to explore the proportion of participants who relapsed in each group. **Definition of relapse/recurrence:** Any major bipolar episode that fulfilled DSM-IV criteria for major depression, mania, or hypomania. **Results:** Significantly fewer relapses (i.e. any bipolar episode that fulfilled DSM-IV criteria for major depression, mania or hypomania) in CT compared with control group. The experimental group had significantly fewer experiences of depressive, manic, hypomanic episodes in 12 month period. The experimental group spent significantly fewer days in hospital for BD episodes. The experimental group had significantly fewer days in hospital for depressive episodes. Mood measures A significant reduction in BDI scores, across time, occurred in the experimental group. There was a significantly greater degree of mood fluctuation in the control group.
Additional information
Are the tests appropriate for the data used: √ Are confounding variables adequately controlled: √ Is the research ethical? √ Is the design ecologically valid? √ Medication adherence controlled? √ Sample size: moderate Treatment fidelity measured: X Methodological quality: high

8. Study name: Lam *et al.* (2005) **county of origin:** United Kingdom

Aims

To investigate long-term effect of CBT at 2 year follow-up to provide an estimate of the enduring effect of cognitive therapy. This study was a follow-up study to Lam *et al.* (2003).

Methods

recruitment: via psychiatrist referral or from maintenance clinic list
allocation: random
blinding: √
research setting: clinical setting
duration of study: 6 months **follow-up period**: 12 months
inclusion criteria: prescribed adequate dose of prophylactic medication; aged 18-70; at least 2 episodes in past 2 years or 3 in past 5 years; not fulfilling criteria for a episode.
exclusion criteria: actively suicidal (assessed by BDI suicide item score of 3); fulfilling criteria for substance use disorder

Participants

diagnosis: Bipolar I according to DSM-IV
matched on demographic variables at baseline: √
matched on illness-related factors (e.g. no. of episodes) at baseline: √

	Control group	**Experimental group**
age:	M= 46.4 (±12.1)	41.5 (±10.8)
female:	28	30
sample size:	51	52
attrition rate:	15.68%	15.68%

no information on marital or employment status.

Intervention description

Control group: TAU
Experimental group: Cognitive Therapy manualised approach (CT) + TAU
CT consisted of 12-18 individual sessions within 6 months and 2 booster sessions in second 6 months administered by 4 Clinical Psychologists (3 male, experience 5 yrs +)
Content of CT: information on diathesis-stress model; CBT for mood monitoring, prodromal monitoring, behaviour modification to manage prodromes, psychoeducation on importance of sleep and routine, work on extreme striving attitudes. Seen for an average of 14 sessions.

Measures

At 6-month intervals blind assessors administered the SCID, HDRS, BRMRS, Coping with Prodromes Schedule, SFS, (patients' description of coping with prodromes was transcribed verbatim), DAS, MCS completed by key workers.

Outcomes

Overview of analysis:
The Chi-Square test was used to analyse dichotomous variables, ANOVA for continuous variables, Cox regression for survival analysis (no. of weeks to first episode entered as a dependent variable), Logistic Regression used to compare proportions of patients who had relapsed in the two groups. ANCOVA used when appropriate.

Definition of relapse/recurrence:
Any major bipolar episode that fulfilled DSM-IV criteria for major depression, mania, or hypomania.

Results:
Survival analysis of number of weeks to first episode:
Significant between-group differences for time to first episode post intervention for depressive but not manic/Hypomanic episodes. With experimental group experiencing bigger time delay.
18 month follow-up:
Non-significant difference in proportion of participants who had at least 1 relapse.
Significant between-group differences for number of days in a bipolar episode (previous episodes and medication compliance controlled for) with experimental group experiencing shorter episodes.
Mood measures (number of previous episodes and medication compliance entered as covariates):
Significant between-group difference for DAS goal attainment at 18 months, social functioning 24 months, coping with mania and depressive prodromes at 24 months, mania ratings at 30 months in terms of the experimental group having significantly better ratings compared to the control group.
Medication:
No significant between-group differences with the exception of number of mood stabilisers prescribed at 18 month period.
Based on self-report measures the experimental group were more compliant at 24 and 30 compared with the control group regarding their medication.

Additional information

Are the tests appropriate for the data used: √
Are confounding variables adequately controlled: √
Is the research ethical? √
Is the design ecologically valid? √
Medication adherence controlled for in analysis: √
Sample size: good
Treatment fidelity measured: √ sessions audio-taped but lack of clarity concerning how this information was used.
Methodological quality: moderate

9. Study name: Perry *et al.* (1999) **county of origin:** United Kingdom

Aims

To determine the efficacy of teaching patients with bipolar disorder to identify early warning symptoms associated with their relapse (both manic and depressive episodes). Also under investigation was whether patients would seek help from health care professionals once early warning symptoms were identified.

Methods

recruitment: Patients with a clinical diagnosis of BD were identified from computerised patient records of hospital admission to 3 NHS trusts. Patients were approached their psychiatrist and key worker thought they were suitable candidates. Patients were also referred for possible study inclusion by consultant psychiatrists and mental health workers in the three trust research sites.
allocation: Random allocation based on four stratification factors: age (18-40 years/41 to 75 years), sex, use of Lithium, and presence/absence of carer (defined as 10hrs of contact with patient – unclear over what time period, e.g. day or week).
blinding: √ single blind randomised controlled trial. (Study raters unaware of conditions but therapists and patients aware of condition.)
research setting: Mental health setting
duration of study: 12 weeks **follow-up period:** 15 months
inclusion criteria: life time diagnosis of BD (assessed by trained research assistants using the SCID-III), 2+ relapses (1 of which occurred in previous 12 months), aged 18-75 years old.
exclusion criteria: inability to read/write in English, substance misuse/dependence as primary problem, organic cerebral cause for BD. No information on how exclusion criteria assessed.

Participants

diagnosis: bipolar disorder (type 1 and type 11 or both)
matched on demographic variables at baseline:
matched on illness-related factors (e.g. no. of episodes) at baseline:

	Control group	**Experimental group**
age at onset:	?	?
median duration of BD:	11 years (2-41)	12 years (2-34)
female:	24	23
sample size:	35	34
attrition rate:	0	1

information on relationship and employment status provided

Intervention description

Control group: Patients in this group received routine care delivered by psychiatrists, key worker, and general practitioner that included drug treatment, mood monitoring, adherence to treatment, support, education about bipolar disorder, and inpatient care (when required).
Experimental group: One research therapist carried out the intervention. A two-stage intervention was used: 1) patients were trained to identify manic and depressive prodromes. 2) An action plan was planned and rehearsed. Prodromal symptom information obtained via card sorting exercise and standard checklist. Diaries used to identify symptoms linked with normal mood variation. The patient identified three health care professionals to approach for early treatment (one of whom would be available at all times). Relapse plan was printed on a laminated card the patient carried.

Measures
Trained research assistants administered the SCID and a measure of social functioning (Hurry *et al.,* 1983). Patients' psychiatrists and key workers were contacted by the research assistant, on a monthly basis, for patient contact and relapse information. If a relapse was identified a research assistant interviewed the patient using the SCID-III to date the relapse. Information on drug treatment and contact with mental health services was collected via the patient files on a six monthly basis by the research assistant.
Outcomes
Overview of analysis Manic and depressive treated as independent variables. Time to relapse analysed using log rank test. The data on relapse was analysed using t-test test, Mann Whitney U tests, and median differences tests with 95% confidence intervals. Intent to treat analysis carried out. **Definition of relapse:** A minimum of 5 days of symptoms of mania, hypomania, mixed affective disorder, or major depression according to standardised symptom criteria (the two week duration criterion for major depression was not adhered to for this outcome measure. **Results** Time to first manic relapse was 65weeks in the experimental group and 17 weeks in the control group (significant between-group difference) and time to first depressive relapse was 21 weeks in the experimental group and 26 weeks in the control group (non significant result). There was no significant difference in length of manic episode between the two groups. 18 months post study there was a significant difference in overall social functioning and employment in the experimental group.
Additional information
Are the tests appropriate for the data used: √ Are confounding variables adequately controlled: √ Are the two groups matched on relevant factors: √ Is the research ethical? √ Is the design ecologically valid? √ Medication adherence controlled for in analysis: √ Sample size: good Treatment fidelity measured: X Methodological quality: moderate

10. Study name: Scott *et al.* 2001 **county of origin:** United Kingdom

Aims

To explore the feasibility and potential benefits of CT (i.e. improved general functioning and reduced relapse and hospitalisation rates) pre, during and post intervention.

Methods

recruitment: A letter was sent to general adult psychiatry working within the Newcastle area asking individuals to refer patients for consideration for study inclusion.
allocation: randomised allocation
blinding: √
research setting: unclear from information provided in the paper
duration of study: 6 months **follow-up period**: 18 months
inclusion criteria: minimum age 18 years old, Bipolar I and II, a minimum of 1+ episode in the last 2 years.
exclusion criteria: Bipolar Disorder secondary to organic disorder, severe physical ill health, cognitive impairment sufficient to impair judgement to consent, unable to willingly give written consent. I
If a potential participant was in an acute setting at time of referral or met criteria for mania they were accepted at point of discharge or when mental state was stable to enable capacity to consent.

Participants

diagnosis: BD I and II
matched on demographic variables at baseline: √
matched on illness-related factors (e.g. no. of episodes) at baseline: √ (* 6 more BDI participants in experimental group)

	Control group	**Experimental group**
age:	37.8 (8.7)	40.5 (6.7)
age at onset:	24.2 (10.5)	24.7 (12.4)
female:	14	11
sample size:	21	21
attrition rate:	6	3

information on employment or marital status

Intervention description

Control group: 6 month WLC who received TAU (i.e. medication, out patient and other services as previously. Participants in this group were given the opportunity to receive CBT once study period completed.
Experimental group: Participants in this group received up to 25 sessions of one to one CT after an initial assessment and TAU. CT included approached for symptom management (self-monitoring), relapse prevention techniques which included prodromal monitoring and coping strategies for identified early warning symptoms. Two therapists with experience in working with severe affective disorders delivered the therapy.

Measures

A semi-structured interview (carried out by an independent psychiatrist) and hospital records were used to gain information on: demographic, pre-morbid personality, social functioning, current and past psychiatric history, current treatments and services received, medication adherence. Independent psychiatrist completed the SADS-L and the GAF. Participant self-report measures: PDQ-R, WASA, ISS, BDI, SCL-90.

Outcomes
Overview of analysis: Chi-square was used to explore baseline differences for dichotomous data, ANOVA used for continuous variables, ANCOVA used to assess change in symptoms and functioning by group and time (covariates: age, age of onset, and gender). To explore pre and post relapse and hospitalisation rates chi-square tests used. Paired t-tests used to explore CT ratings. **Definition of relapse/recurrence:** When participants meet diagnostic criteria for an affective episode. **Results:** No between-group differences observed or age, gender, illness-related factors, and personal characteristics. Five participants in the experimental group and 7 in the control group met criteria for drug/alcohol dependence/problems, 60% of participants met criteria for personality disorder (BD – 15, antisocial – 11, 14 participants met criteria for 1+ disorders). No significant difference was found on symptom ratings at baseline. WLC showed little change between baseline and 6 month assessment whereas the CT group showed a significant reduction in the following mood measures: BDI, ISS Dep, ACT, PC and GAF. A non-significant improvement was noted in the ISS_WB, CL-90 and WASA data. When WASA subscale analysis was done a significant improvement in the CT group found for social activities involving others. No between-group was observed fro medication or TAU received. Relapse rates: A greater reduction in symptoms that met diagnostic criteria for affective episode observed in the CT group but effect not significant. Changes in symptoms and functioning (data from 29 participants including those who took part in the control group but later took up offer of CT): A significant reduction in symptoms and improvement in functioning found immediately following CT compared with pre-CT ratings for following measures: GAF, WASA, BDI, ISS Dep, ISS ACT, Scl-90). A significant improvement also found pre CT and at follow-up 18 months, however an increase in symptoms was observed. A significant change in mental state over time also observed with fewer people meeting criteria for relapse or persistent illness after CT. Hospital admission rates were also lower: 1 year pre CT: 38%, during CT: 0%, and 1 year post CT: 7%.
Additional information
Are the tests appropriate for the data used: √ Are confounding variables adequately controlled: √ Is the research ethical? √ Is the design ecologically valid? √ Medication adherence controlled for in analysis: X but no significant between-group differences Sample size: moderate Treatment fidelity measured: X Methodological quality: moderate

11. Study name: Simon *et al.* (2005) **county of origin:** USA

Aims

To evaluate a multi-component care management programme for people with Bipolar disorder.

Methods

recruitment: Patients were enrolled at a Model Behaviour Health clinics. Potential participants identified through computerised visits and hospital records. People with a diagnosis of Bipolar I and II were invited to a baseline assessment.
allocation: random
blinding: √
research setting: clinical setting
duration of study: unclear **follow-up period**: 12 months
inclusion criteria: minimum age of 18 years old, diagnosis of BD I and II confirmed by SCID or a record review.
exclusion criteria: cognitive impairment severe enough to preclude ability to consent.

Participants

diagnosis: BD I and II
matched on demographic variables at baseline: √
matched on illness-related factors (e.g. no. of episodes) at baseline: ?

	Control group	Experimental group
Age at onset:	44.3 (12.9)	44.1 (13.4)
female:	157	144
sample size:	229	212
attrition rate:	14	13

Intervention description

Control group: TAU
Experimental group: Received initial assessment (which included typical early signs of mood episodes and coping strategies) and care planning structured monthly telephone monitoring of mood symptoms and medication use, feedback to mental health team, additional support when required (e.g. crisis intervention) and a structured psychoeducation group. Care managers (nurse care managers with at least 5 years clinical experience) provided the above treatment. A collaborative treatment plan was developed based on assessment information. The group programme was adapted from Bauer and McBride's Life Goals Program (Bauer and McBride, 2003). Group consisted of 5 weekly sessions followed by twice monthly sessions for duration of intervention. Phase 1 included early symptom monitoring and coping strategies, education about bipolar disorder, and triggers. Phase 2 focused on life goals. Information on self-management plans (e.g. early symptom monitoring were also updated in phase 2).

Measures

SCID (at assessment and to confirm a suspected relapse), ISS (monthly), medication use record, PSR score based on information from SCID. At follow-up SCID and LIFE administered. Follow-up measures were administered every 3 months. The follow-up was carried out by mental health clinicians with 1+ years experience assessing mood disorders. Individuals received training.

Outcomes
Overview of analysis: Repeated measures linear model with relevant baseline characteristics used (age, sex, depression severity, mania severity, psychological symptoms, substance abuse and recent hospitalisations). Intent to treat analysis carried out. **Definition of relapse/recurrence:** Defined as the clinical cut-offs on the SCID Psychiatric Status Rating scale **Results:** Mania scores The treatment group had significantly lower scores over 12 month period for mania symptoms. No significant between-group scores found for time with mania symptoms. There was a significant between-group effect for time spent in hospital (manic episode) with fewer individuals in the experimental group having spent time in hospital. Depression No significant between-group difference was found for depressive scores throughout the follow-up period. A significant group x time interaction was found – depressive symptoms in the experimental group showed larger decline over time. Medication No significant between-group difference for medication (it is however unclear how or whether medication adherence was monitored.)
Additional information
Are the tests appropriate for the data used: √ Are confounding variables adequately controlled: √ Is the research ethical? √ Is the design ecologically valid? √ But issues with generalisability to other health care centres Medication adherence controlled for in analysis X Sample size: √ but below the number given by the power calculation. Treatment fidelity measured: X Methodological quality: high